MEDICAL POLICY

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MEDICAL POLICY DETAILS	
Medical Policy Title	**Minimally Invasive Treatments for Benign Prostatic Hyperplasia (BPH)**
Policy Number	**7.01.104**
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Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), 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 STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, **prostatic urethral lift (PUL**) (i.e., **UroLift**) has been medically proven to be effective and, therefore, is considered **medically appropriate** for patients with symptomatic benign prostatic hyperplasia (BPH) who meet **ALL** of the following criteria and may desire preservation of erectile and ejaculatory function:
   A. persistent or progressive, moderate-to-severe lower urinary tract symptoms despite medical therapy (e.g., alpha blocker, PDE5 Inhibitor, finasteride/dutasteride) for at least three months or inability to tolerate medical therapy for BPH; **AND**
   B. estimated prostate volume less than 80 cc; **AND**
   C. no obstructive median lobe of the prostate identified on cystoscopy; **AND**
   D. no signs or symptoms of urinary tract infection (UTI).

II. Based upon our criteria and assessment of the peer-reviewed literature, **transurethral water vapor thermal therapy II** (i.e., Rezūm) has been medically proven to be effective and, therefore, is considered **medically appropriate** for patients with symptomatic BPH, who may desire preservation of erectile and ejaculatory function, and who meet **ALL** of the following criteria:
   A. persistent or progressive, moderate-to-severe lower urinary tract symptoms despite medical therapy (e.g., alpha blocker, PDE5 Inhibitor, finasteride/dutasteride) for at least three months or inability to tolerate medical therapy for BPH; **AND**
   B. age 50 years or older; **AND**
   C. estimated prostate volume 30-80 cc**; AND**
   D. individual is a poor candidate for other surgical interventions for BPH, or the individual opts to undergo a minimally invasive procedure.

III. Based upon our criteria and assessment of the peer-reviewed literature, **Waterjet Ablation Therapy (Aquabeam)** has been medically proven to be effective and, therefore, is considered **medically appropriate** for patients with

symptomatic BPH who may desire preservation of erectile and ejaculatory function, and who meet **ALL** of the following criteria:
A. Age 45-80yrs; **AND**
B. Estimated prostate volume 30-80cc; **AND**
C. Has benign prostatic enlargement causing bladder outlet obstruction.

IV. Based upon our criteria and assessment of the peer-reviewed literature, **PUL *(i.e., UroLift)*** and **transurethral water vapor thermal therapy (i.e., Rezūm)** for all other indications, have not been medically proven to be effective and, therefore, are considered **investigational.**

V. Based upon our criteria and assessment of the peer-reviewed literature, **prostate artery embolization (PAE)** has not been medically proven to be effective and, therefore is considered **investigational** for patients as a treatment for BPH.

VI. Based upon our criteria and assessment of the peer-reviewed literature, **transperineal laser ablation (TPLA)** has not been medically proven to be effective and, therefore is considered **investigational** for patients as a treatment for BPH.

VII. Based upon our criteria and assessment of the peer-reviewed literature, **temporary implantable nitinol device (iTIND)** has not been medically proven to be effective and, therefore is considered **investigational** for patients as a treatment for BPH.

Refer to Corporate Medical Policy #7.01.01 Focal Therapies for Prostate Cancer

Refer to Corporate Medical Policy #11.01.03 Experimental and Investigational Services

POLICY GUIDELINE

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 to five implants per 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).

UroLift System (NeoTract Inc., Pleasanton, CA) is a minimally invasive, prostatic urethral lift (PUL) system 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 generally implanted by a urologist in an outpatient or inpatient setting. The transurethral procedure to insert the UroLift is performed with the use of local or general anesthesia and oral sedation. 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. The UroLift System should not be used if the patient has a prostate volume of >100 cc, a urinary tract infection (UTI), urethra conditions that may prevent insertion of delivery system into bladder, urinary incontinence due to incompetent sphincter, current gross hematuria. 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. This indication has not been supported by the American Urological Association 2021 updated guidelines.

Transurethral water vapor thermal therapy has been investigated as a minimally invasive alternative to transurethral resection of the prostate. The Rezūm System (NxThera, Inc., Maple Grove, MN) received Section 510(k) approval from the FDA in August 2015. The FDA indications for use state that the Rezūm System is intended to relieve symptoms, obstructions, and reduce prostate tissue associated with BPH. It is indicated for men ≥ 50 years of age with a prostate volume ≥ 30 cm3 and ≤ 80 cm3. The Rezūm System is also indicated for treatment of prostate with hyperplasia of the central zone and/or median lobe. 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.

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's causing the swelling in the prostate.

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.

iTIND, the temporary implantable nitinol device (iTIND MediTate Ltd., Israel), 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.

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. Study conclusions are there is a lack of long-term data available for the new device and therefore, the durability of this procedure is yet to be established at this time. While at present, only limited evidence exists to support its use, early results of this modified version are very promising. Key advantages include a strong safety profile and preservation of existing sexual function. Future studies are awaited to help delineate its formal role in current treatment algorithms. While the formal position of iTIND in current guidelines is yet to be determined, 12-month data demonstrates that it can improve both objective and subjective outcome measures, which are sustained at short-term follow up.

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.

RATIONALE

Prostatic Urethral Lift

In 2013, Roehrborn et al. 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), 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 (peak urinary flow rate) 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 AEs (postoperative dysuria, hematuria, pain/discomfort, and urgency) were typically mild to moderate and resolved within two weeks. The authors concluded 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.

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.

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.

In 2017, Gratzke et al. 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 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.

The American Urological Association (AUA) addresses PUL in the evidence-based guideline, "Surgical Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia (amended 2020)." The guideline states, "Clinicians should consider PUL as an option for patients with LUTS attributed to BPH provided prostate volume <80g and verified absence of an obstructive middle lobe; (Moderate Recommendation; Evidence Level: Grade C)." The supporting text was revised to clarify the results of two RCTs: the BPH6 Study and the L.I.F.T study. The guideline further states, "PUL may be offered to eligible patients concerned with erectile and ejaculatory function for the treatment of LUTS attributed to BPH. (Conditional Recommendation; Evidence Level: Grade C)." The AUA referenced the L.I.F.T study along with the study limitation of PUL to prostates less than 80g. It is recommended that clinicians limit this procedure to individuals with prostates less than 80g, until further data is available to indicate safety in other populations.

An additional evidence-based guideline was added in the 2020 AUA amendment recommending that patients be counseled as to the potential risks of treatment failure and need for additional therapies. (Clinical Principle)

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 age 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.

The American Urological Association (AUA) addresses transurethral water vapor thermal therapy in the evidence-based guideline, "Surgical Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia (amended 2021)." Water vapor thermal therapy may be offered to patients with LUTS attributed to BPH provided prostate volume less than 80g. (Moderate Recommendation; Evidence Level: Grade C). An additional guideline added states "water vapor thermal therapy may be offered to eligible patients concerned with erectile and ejaculatory function for the treatment of LUTS attributed to BPH. (Conditional Recommendation; Evidence Level: Grade C)."

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.

In summary, the 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.

Prostate artery embolization (PAE)

The American Urological Association (2021) guidelines state 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)

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, 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.

Transurethral Waterjet Ablation (Aquablation)

The American Urological Association (AUA) 2021 guidelines on the surgical evaluation and treatment of lower urinary tract symptoms (LUTS) attributed to benign prostatic hyperplasia (BPH) states that robotic waterjet treatment may be offered as a treatment option to patients with LUTS/BPH provided prostate volume is 30 to 80cc. (Conditional recommendation; Evidence Level: Grade C)

The National Institute for Health and care Excellence (NICE) 2021 guidelines for Transurethral water jet ablation for LUTS/BPH states that evidence on transurethral water jet ablation for lower urinary tract symptoms caused by benign prostatic hyperplasia raises no major safety concerns. The evidence on efficacy is limited in quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

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 ages45 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% vs. 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).

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
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)
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 *(effective 07/01/2024)*
37243 **(E/I)**	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 (PAE)
52441	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant
52442	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; each additional permanent adjustable transprostatic implant (List separately in addition to code for primary procedure)
53854	Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy
53865 **(E/I)**	Cystourethroscopy with insertion of temporary device for ischemic remodeling (ie, pressure necrosis) of bladder neck and prostate *(effective 1/01/2025)*
53866 **(E/I)**	Catheterization with removal of temporary device for ischemic remodeling (ie, pressure necrosis) of bladder neck and prostate *(effective 1/01/2025)*

HCPCS Codes

Code	Description
C9739	Cystourethroscopy, with insertion of transprostatic implant; one to three implants
C9740	Cystourethroscopy, with insertion of transprostatic implant; four or more implants
C9769 **(E/I)**	Cystourethroscopy, with insertion of a temporary prostatic implant/stent with fixation/anchor and incisional struts

ICD10 Codes

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

REFERENCES

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*Key Article

KEY WORDS

Rezūm, UroLift, transurethral water vapor thermal therapy, prostatic urethral lift, Prostate artery embolization (PAE), Transperineal laser ablation (TPLA), temporary implantable nitinol device (iTIND).

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a Local Coverage Determination (LCD), Water Vapor Thermal Therapy for LUTS/BPH (L37808)

Please refer to the following LCD website for Medicare Members https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=37808 accessed 06/27/23.

Based on our review, prostatic urethral lift is not addressed in National or Regional Medicare coverage determinations or policies.

There is currently a Local Coverage Determination (LCD) Fluid Jet System Treatment for LUTS/BPH (L38367) Please refer to the following LCD website for Medicare Members: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=38367&ver=24 accessed 06/27/23.

There is currently a Local Coverage Article (LCA), Billing and Coding: Fluid Jet System Treatment for LUTs/BPH (A56797) Please refer to the following LCA website for Medicare Members: https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=56797&ver=8&keyword=&keywordType=starts&areaId=s41&docType=6,3,5,1,F,P&contractOption=all&hcpcsOption=code&hcpcsStartCode=0421T&hcpcsEndCode=0421T&sortBy=title&bc=1 accessed 06/27/23.

There is currently a National Coverage Determination (NCD) Therapeutic Embolization for hemorrhage, and for other conditions amenable to treatment by the procedure, when reasonable and necessary for the individual patient (20.28). Please refer to the following NCD website for Medicare Members: https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=52 accessed 06/27/23.