# Benign Prostatic Hyperplasia Treatments

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**INSTRUCTIONS FOR USE:** Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

**SCOPE:** Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

## *PLAN PRODUCT AND BENEFIT APPLICATION*

☒ **Commercial** ☒ **Medicaid/OHP*** ☐ **Medicare****

*Medicaid/OHP Members

*Oregon*: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

## COVERAGE CRITERIA

**Water Vapor Thermoplasty**

I. Water vapor thermotherapy (i.e. Rezūm System) may be considered **medically necessary** for the treatment of benign prostatic hyperplasia (BPH) when all of the following criteria (A.-E.) are met:

   A. Patient is at least 50 years of age; **and**
   B. Patient has moderate-to-severe chronic lower urinary tract symptoms (defined as an American Urologic Association or International Prostate Symptom Score ≥ 8); **and**
   C. Documented failure, contradiction, intolerance, or individual non-acceptance of pharmacological management; **and**
   D. Prostate volume is at least 30 $cm^3$; **and**
   E. Prostate volume is no greater than 80 $cm^3$.

II. Water vapor thermotherapy (i.e., Rezūm System) is considered **not medically necessary** when criterion I. above is not met.

**Prostatic Urethral Lift**

III. The prostatic urethral lift (PUL) procedure (i.e. UroLift®) may be considered **medically necessary** for the treatment of symptomatic benign prostatic hyperplasia (BPH) when all of the following criteria (A.-D.) are met:

   A. Patient is age 45 or older; **and**

B. Patient has moderate-to-severe chronic lower urinary tract symptoms (defined as an American Urologic Association or International Prostate Symptom Score ≥8); **and**
C. Documented failure, contradiction, intolerance, or individual non-acceptance of pharmacological management; **and**
D. Patient meets all of the following indications for the PUL procedure (1.-6.):
   1. Has a prostate volume less than 100cc; **and**
   2. Does not have an obstructive or protruding median lobe of the prostate; **and**
   3. Does not have a urethra condition that may prevent insertion of delivery system into bladder; **and**
   4. Does not have an active urinary tract infection (UTI); **and**
   5. Urinary incontinence is not due to an incompetent sphincter.

IV. The prostatic urethral lift is considered **not medically necessary** when criterion III. above is not met.

V. Repeat prostatic urethral lift procedures are considered **medically necess**ary when criterion III. (A-D) is met.

**Transurethral Waterjet Ablation**

VI. Transurethral waterjet ablation (i.e., AquaBeam by Procept BioRobotics) may be considered **medically necessary** for the treatment of symptomatic benign prostatic hyperplasia (BPH) when all of the following criteria (A.-E.) are met:

A. Patient is at least 45 years of age; **and**
B. Patient has moderate-to-severe chronic lower urinary tract symptoms (defined as an American Urologic Association or International Prostate Symptom Score $\geq$ 8); **and**
C. Documented failure, contradiction, intolerance, or individual non-acceptance of pharmacological management; **and**
D. Prostate volume is at least 30 $cm^3$; **and**
E. Prostate volume is no greater than 80 $cm^3$.

VII. Transurethral waterjet ablation (e.g., AquaBeam by Procept BioRobotics) is considered **not medically necessary** for the treatment of benign prostatic hyperplasia when criterion VI. above is not met.

**Not Medically Necessary Treatments of BPH**

VIII. Transperineal laser ablation is considered **not medically necessary** for the treatment of benign prostatic hyperplasia.

IX. Temporary prostatic urethral stent placement is considered **not medically necessary** for the treatment of benign prostatic hyperplasia.

Link to Evidence Summary

## POLICY CROSS REFERENCES

None

**The full Company portfolio of current Medical Policies is available online and can be accessed here.**

## POLICY GUIDELINES

**BACKGROUND**

**Benign Prostatic Hyperplasia**

Benign Prostatic Hyperplasia (BPH) is an enlargement of the prostate gland. The prostate gland sits below the bladder and encircles the urethra (the tube that carries urine out of the body). The prostate naturally grows with age, and as it grows it can begin to compress the urethra and because of this, BPH is very common in aging men. Approximately 50% of all men age 51 to 60 have BPH, and approximately 90% of men over the age of 80 have BPH.[1] Many men with BPH do not have symptoms. Men that do have symptoms usually experience frequent urination, a weak urine stream, and/or leaking urine. These BPH symptoms are commonly referred to as lower urinary tract symptoms (LUTS). The treatment for LUTS usually depends on the severity of symptoms. Men with mild BPH may start with life style changes; while men with moderate-to-severe BPH typically require treatment with medications and possibly surgery.[2]

**Treatment of Benign Prostatic Hyperplasia**

Pharmacologic Therapy

There are two types of medicines used to treat BPH: alpha blockers and alpha-reductase inhibitors. Typically, men who start taking BPH medicine will need to take it forever unless surgical treatment is undertaken.[2] Alpha blockers may be used to treat LUTS related to BPH by relaxing the muscles of the prostate and bladder neck; thus reducing the pressure on the urethra and more urine flow. Alpha blockers begin to work quickly and are usually recommended as the first-line of treatment for mild-to-moderate BPH symptoms.[2] Alpha-reductase inhibitors stop the prostrate from growing and can even cause it to shrink. This type of medication is recommended for men with larger prostates and can take up to six months for symptom improvement. Common side effects of both BPH medicines include dizziness, loss of libido, and sexual dysfunction. These side effects and the need for life-long BPH medication compliance, lead 30% of men to discontinue their BPH medicine after the first year.[3]

Transurethral Resection of the Prostate (TURP)

TURP is a surgical treatment for BPH that involves the removal of obstructing tissue from the prostate. In the United States, about 150,000 men have TURPs each year.[4] The procedure is typically performed under general or spinal anesthesia and requires a 24-48 hour postoperative catheterization observation period. The average recovery time after the TURP procedure is anywhere from 4 to 12 weeks, and patients may also experience a postoperative worsening of LUTS for 4 to 6 weeks. On average, TURP results in a 14.9 International Prostate Symptom Score (IPSS) improvement; therefore making it the gold

standard surgical intervention for treatment of BPH.[5] However, due to the invasive nature of the TURP procedure it is associated with more serious and possibly chronic complications including loss of ejaculatory function (65%), erectile dysfunction (10%), incontinence (3%), excessive bleeding requiring transfusion (2.9%), transurethral resection syndrome (1.4%), and stricture formation (7%).[5,6] Although the TURP procedure significantly improves LUTS, these potential adverse side effects could considerably impact a patient's quality of life; therefore, new surgical techniques have been proposed as less invasive alternatives to TURP.

The Rezūm System

According to Hayes:

> "The Rezūm System [i.e. Rezūm] is a minimally invasive, transurethral treatment for BPH that utilizes convective radiofrequency water vapor energy to ablate the hyperplastic tissue. The Rezūm System consists of a radiofrequency power generator and a disposable delivery device. The rigid shaft of the delivery device incorporates a standard lens so that the procedure may be performed under cystoscopic visualization. The delivery device also contains a needle, which injects wet thermal energy (i.e., steam) into diseased prostatic tissue. The steam immediately condenses to water thereby dispersing thermal energy and killing the surrounding cells. The dead cells are eventually absorbed, which reduces the volume of prostatic tissue and opens the urethra … Once the Rezūm delivery device is within the prostate, the needle is deployed and a 9-second burst of 103˚C water vapor is injected into the prostatic tissue creating a spherical lesion of 1.5 to 2 centimeters (cm). The total number of treatments in each lobe is based upon the length of the hyperplastic prostatic tissue and the length of the urethra, but typically 1 to 3 sites are treated per lobe. The goal is to create contiguous, overlapping lesions approximately 1 cm apart along the urethra."[7]

Prostatic Urethral Lift (PUL) (UroLift®)

The PUL procedure (i.e. UroLift®) is a surgical treatment for BPH that involves the placement of small mechanical sutures which hold the enlarged prostate tissue out of the way so it no longer blocks the urethra.[8] This is done by placing small, non-absorbable suture implants with a metallic anchor into the lateral (side) lobes of the prostate. These sutures mechanically separate the lobes in order to help relieve pressure and increase the opening of the urethra. Four to five implants are usually inserted, but this number varies with the size and shape of the prostate.10 Since the PUL procedure does not remove any obstructing prostate tissue and typically only requires local anesthesia, it is less invasive than other surgical BPH treatments. PUL is typically performed in the doctor's office by an appropriately trained urologist.

Transperineal Laser Ablation

Transperineal Laser Ablation is an alternative to other minimally invasive treatments for BPH. Unlike Holmium or thulium laser enucleation, the treatment is transperineal rather than transurethral—that is, the surgeon uses a percutaneous approach through the skin of the perineum, between the patient's genitals and anus.[9]

Transurethral Waterjet Ablation

Transurethral Waterjet Ablation (i.e. Aquablation), sometimes referred to as Robotic waterjet treatment (RWT), is a technique that uses an image-guided, robotically controlled waterjet to ablate prostatic tissue. [4] The waterjet serves as a high-velocity hydrodissection tool, heat-free, that ablates the tissue while sparing major blood vessels and the prostatic capsule. This procedure is not considered a minimally invasive surgical treatment (MIST) as patients must undergo general anesthesia.

Temporary Prostatic Urethral Stents

Temporary Prostatic Urethral Stents (i.e. iTind®, The Spanner®) is a temporary, implantable prostatic tissue retractor system intended to treat the urinary symptoms of BPH by reshaping and expanding the bladder neck and prostatic urethra. This minimally invasive treatment option intended to result in fewer side effects than more invasive treatments.[10] iTind is made of nitinol super elastic shape memory alloy and biocompatible material that is supplied in a folded configuration and that expands during implantation. The first-generation (TIND) design comprised four struts and an anchoring leaflet, with the struts coming to a point at the tip to hold them together, with soft plastic covering the tip to prevent bladder injuries. The second-generation iTind design comprises three struts and an anchoring leaflet, which do not come to a pointed tip. iTind has its own delivery system and is implanted during an outpatient procedure. iTind is implanted through a cystoscope and, upon implant deployment, expands to a maximum diameter of 33 mm and a length of 50 mm. After implantation, the three nitinol struts apply continuous pressure on the surrounding tissue, which causes subsequent tissue necrosis, reshaping and expanding the bladder neck and prostatic urethra. iTind remains in place for five to seven days, then is removed in the urologist's office by pulling the polyester retrieval suture through an open-ended catheter.

## *REGULATORY STATUS*

**U.S. FOOD AND DRUG ADMINISTRATION (FDA)**

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

**FDA 510(k) Premarket Notifications and De Novo clearances:**

| Device and Company | Indications for Use | Contraindications |
|---|---|---|
| Rezum system by NxThera Inc. | The Rezum™ 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 30cm3 ≤ 80cm$^3$. The Rezum System is also indicated for | The use of the Rezūm System is contraindicated for the following:<br><br>• Patients with a urinary sphincter implant<br>• Patients who have a penile prosthesis |

| | | |
|---|---|---|
| | treatment of prostate with hyperplasia of the central zone and/or a median lobe. [11] | |
| Urolift System by NeoTract Inc.[12] | The UroLift System is indicated for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men age 50 and above. | The UroLift® System should not be used if the patient has:<br>• Prostate volume of >80 cc<br>• An obstructive or protruding median lobe of the prostate<br>• A urinary tract infection<br>• Urethra conditions that may prevent insertion of delivery system into bladder<br>• Urinary incontinence<br>• Current gross hematuria<br>• A known allergy to nickel |
| Aquabeam System by Procept BioRobotics Corporation[13] | The AQUABEAM System is intended for the resection and removal of prostate tissue in males suffering from lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia. | Do not use the Aquabeam System in patients with:<br>• Active urinary tract or systemic infection<br>• Known allergy to device materials<br>• Inability to safely stop anticoagulants or antiplatelet agents perioperatively<br>• Diagnosed or suspected cancer of the prostate |
| Visualase Thermal Therapy System by Biotex, Inc[14] | The Visualase Thermal Therapy System is indicated for use to necrotize or coagulate soft tissue through interstitial irradiation or thermal therapy under magnetic resonance imaging (MRI) guidance in medicine and surgery in cardiovascular thoracic surgery (excluding the heart and the vessels in the pericardial sac), dermatology, ear-nose-throat surgery, gastroenterology, general surgery, gynecology, head and neck surgery, neurosurgery, plastic surgery, orthopedics, pulmonology, radiology, and urology, for wavelengths 800nm through 1064nm. | |

## CLINICAL EVIDENCE AND LITERATURE REVIEW

**EVIDENCE REVIEW**

**Water Vapor Thermoplasty**

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of the Rezūm System (Boston Scientific Corp.) as a treatment for benign prostatic hyperplasia. Below is a summary of the available evidence identified through August 2023.

Systematic Reviews

- In 2016 (updated with new studies in 2022), ECRI conducted an evidence review assessing the safety and efficacy of Rezūm for the treatment of benign prostatic hyperplasia.[15] Searching the literature through December 2021, ECRI reviewed the full texts of four systematic reviews, one RCT, and three economic studies reporting on 7,797 patients (total number of patients overlap between studies). Indirect comparisons for TURP and minimally invasive therapies from mostly low- and very-low-quality studies found mixed results on effectiveness with Rezūm being less effective than or similarly effective to other minimally invasive therapies and TURP. Three economic studies estimated lower costs with Rezūm than with TURP or prostatic urethral lift (PUL), but higher costs than holmium laser enucleation of prostate (HoLEP). ECRI concludes that evidence shows that Rezūm is safe and improves LUTS and quality of life through one-year follow-up compared with baseline. Limitations of studies included patients were allowed to cross over from sham control to Rezūm at three-month follow-up in one RCT. There was also high attrition at five-year follow-up and most studies were at high risk of bias from small sample sizes and lack of randomization and blinding to enable conclusion on comparative effectiveness. Baseline prostate volume also varied between and within studies, which could affect comparative outcomes. ECRI gave an evidence bar rating of evidence is somewhat favorable.

- In 2021 (and updated in 2022) Hayes conducted a health technology assessment evaluating the Rezūm System for the treatment of lower urinary tract symptoms (LUTS) in men with benign prostatic hyperplasia (BPH).[16] Ten eligible studies, in 15 publications, were reviewed, including: one RCT, two retrospective cohort studies, five retrospective pretest-posttest studies, and two prospective pretest-posttest studies. The analysis showed Rezūm improving from baseline (and in one study, compared to sham) in quality of life (QOL, International Prostate Symptom Scores (IPPS), urinary flow rate, post void residual (PVR), and IPPS-QOL scores. In the available data that compared Rezūm to prostatic urethral lift (PUL), there were mixed results in patient outcomes, frequently without statistically significance. Hayes ultimately assigned a “C” rating for use of Rezūm in men with LUTS secondary to BPH due to the low-quality body of evidence suggests that Rezūm may alleviate LUTS associated with BPH at short- to intermediate-term follow-up periods without impact on sexual function or serious safety issues. However, uncertainty remains due to the lack of good quality studies comparing Rezūm with alternative surgical interventions (particularly TURP) and the limited long-term evidence regarding the durability and safety of Rezūm.

- In 2020, Miller et al conducted an industry-funded systematic review and meta-analysis of water vapor thermal therapy for lower urinary tract symptoms secondary to benign prostatic hyperplasia.[17] Five cohorts from 4 studies were reviewed, reviewing data from 514 total. The review found that international prostate symptom score, IPSS quality of life, benign prostatic hyperplasia impact index, and maximum flow rate were all improved from baseline. Surgical treatment rates were 2.4% at year one, 5.3% at year 2, 6.3% at year 3, and 7.0% at year 4 of follow-up. These studies, already reviewed in the above Hayes and ECRI reports, and this review suffer from a number of limitations. Only one study was randomized, and only participants receiving water vapor thermal therapy were included in analysis. The other 4 studies were small, had short follow-up and had high heterogeneity. There was no comparator, and no conclusions can be made about the efficacy of water vapor thermal therapy compared to standard of care treatments.

Randomized Controlled Trials

- In 2019, McVary and colleagues conducted a manufacturer-funded randomized controlled trial reporting lower urinary tract symptoms (LUTS) associated with BPH in patients receiving Rezūm.[18] In total, 188 patients with International Prostate Symptom Score ≥13, with a maximum flow rate (Qmax) ≤ 15mL/s and prostate volume 30 to 80cc were treated and followed for 4 years. A subset of 53 patients who initially received sham treatment "crossed over" to active treatment after unblinding at 3-months. This group was followed for 3 years. Results indicated significant improvement in both groups' LUTS and quality of life within 3 months of treatment, sustained throughout 4 years ($p < 0.0001$). Results' validity may be limited by the investigators' financial conflicts of interest with Rezūm's manufacturer, the lack of treatment groups receiving an alternative BPH therapy, narrow inclusion criteria (e.g. all patients 50 years old, without history of urinary retention or UTI) and significant loss to follow-up (primary group: 32.8%, n = 44/134; cross-over group 45.3% n = 24/53). Investigators concluded that Rezūm can provide effective symptom relief and improve quality of life for patients with BPH.

**Prostatic Urethral Lift (PUL)**

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of prostatic urethral lift procedure (PUL) (UroLift®) as a treatment for lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia (BPH). Below is a summary of the available evidence identified through August 2023.

Systematic Reviews

- In 2019, Cochrane published a systematic review evaluating the safety and efficacy of prostatic urethral lift (PUL) for the treatment of lower urinary tract symptoms (LUTS) in patients with benign prostatic hyperplasia (BPH).[19] Systematically searching the literature through January 2019, investigators identified eligible studies, assessed study quality, extracted data and pooled results. Inclusion criteria were limited to parallel group RCTs. In total, 2 RCTs (n=297) comparing PUL to either sham surgery or TURP were included for review. Outcomes of interest included LUTS scores, quality of life, erectile function, ejaculatory function, adverse events and retreatment rates. The study comparing PUL to sham treatment reported clinically significant improvements in PUL patients' urological symptom scores and quality of life. No significant

difference was reported in patients' erectile function or ejaculatory function. Evidence of adverse events was assessed as being of "very low certainty"; no retreatments were reported in either treatment arm at 3-month followup. The study comparing PUL to TURP reported outcomes of 91 randomized patients at 12-months follow-up. Investigators concluded that PUL "may result" in substantially less improvement in urological symptom scores relative to TURP, and in comparable or slightly reduced quality of life. Evidence was "very uncertain" regarding whether PUL may cause fewer major adverse events but increased retreatments. At 2-year follow-up, compared to TURP, PUL patients experienced substantially less improvement in urological symptom scores and "little worse to no difference" quality of life scores.

Limitations of studies included lack of blinding in participants and assessors, lack of long-term follow-up and lack of published RCTs more broadly. Due to the paucity of evidence, investigators were unable to perform any of the predefined secondary analyses for either comparator group. Authors concluded that PUL appears to be less effective than TURP in improving urological symptoms at short-term follow-up (i.e. ≤ 2 years). Evidence was uncertain regarding major adverse events, retreatment rates, erectile function and ejaculatory function. Investigators called for additional, higher-quality studies comparing PUL to TURP and other treatment modalities with long-term follow-up.

- In 2019, ECRI published a systematic review[20] assessing evidence published since their (abovementioned) 2017 review (discussed below). Investigators limited literature searches to between May 2016 and June 2019. In total, ECRI included 3 studies for review (2 case series, 1 cost-effectiveness study). The first case series reported on international prostate symptom score (IPSS), quality of life, BPH impact index (BPHII) and sexual function among 45 patients with obstructive median lobes at 1-year follow-up.10 Limitations included the study's small sample size, lack of long-term follow-up, "significant differences"10 among patients' characteristics at baseline, lack of randomization, blinding and a comparator group. The second case series reported pre- and postprocedure outcomes at 5-year follow-up for 87 patients allocated to the prostatic urethral lift treatment arm of the LIFT study discussed below. The study's validity was limited by its small sample size, but reported 36% superior IPSS improvement compared to patients receiving sham treatment, as well as 61% comparative improvement in quality of life and 70% comparative improvement in BPHII. Investigators concluded that evidence is "somewhat favorable" in support of PUL compared to sham treatment in improving LUTS and quality of life. Nonetheless, authors called for additional RCTs comparing PUL to TURP to further validate findings, assess long-term efficacy, and assess overall efficacy in patients with median lobe obstruction.

- In 2017, ECRI published a health technology assessment of the UroLift® procedure for treating BPH symptoms.[21] The authors systematically searched for relevant research published between January 2011 and October 2016 and included three systematic reviews and two randomized controlled trials (RCTs). The evidence suggested that the UroLift® procedure was well-tolerated and works as intended for treating BPH symptoms in most patients for up to three years.11 The ECRI authors also identified the potential benefit of UroLift® for preserving sexual function and quality of recovery compared to TURP. However, 10.7% of UroLift® treated patients experienced treatment failure that required surgical re-intervention. The assessment also noted that 363 UroLift-related complications had occurred across 7 studies, but more than 95% of these complications resolved without medical intervention. Ultimately, the ECRI assessment

acknowledged the promising technology of the UroLift procedure, but concluded that future RCTs are needed to confirm the results.

- In 2020 (updated in 2023), Hayes published a systematic review which included 9 clinical studies (1 sham-controlled randomized controlled trial (RCT), 1 RCT comparing PUL with TURP, and 7 single-arm observational studies) ) that evaluated the efficacy and safety of the PUL procedure using the UroLift® system for treatment of LUTS related to BPH.[22] The systematic review suggested that PUL was superior to TURP in regards to improvement of the International Prostate Symptom Score (IPSS) and Benign Prostatic Hyperplasia Impact Index (BPHII), early relief of BPH symptoms, and preserving sexual function. However, TURP was reported as superior to UroLift® at improving post-void residual volume (PVR) and peak urinary flow rate (Qmax). The included studies reported minor adverse events, such as dysuria (pain when urinating), hematuria (blood in urine), pelvic pain, and urinary tract infections (UTIs). Hayes stated that the UroLift® device does not appear to compromise sexual function and that the adoption of this device, in appropriately selected patients, may reduce the utilization of inpatient hospital services that are required for more invasive procedures; both of which were reported as significant advantages of this device compared to TURP. Hayes considered the studies included in the review to be of low-quality due to small sample sizes, limited follow-up time, and losses to follow-up. Hayes gave an overall "C" rating for use of the UroLift® System as a treatment of LUTS caused by BPH. This rating was based on the low-quality body of evidence noted above and the, "substantial uncertainty that remains due to the dearth of comparative studies and limited long-term evidence regarding the durability and safety of this device."[22]

- In 2020, Miller and colleagues published a systematic review and meta-analysis on surgical reintervention rates after prostatitic urethral lift.[23] Eleven studies totalling 2016 patients were included in the analysis. Nine studies were observational (4 of which were prospective), and 2 were RCTs (one comparing PUL to TURP and another comparing PUL to sham procedures). All studies were also analyzed in the Hayes review above. The authors found that 153 surgical interventions were performed, 51.0% were TURP, 32.7% were repeat PUL, and 19.6% were device explant. The annual rate of reintervention was 6.0% per year (95% CI, 3.0-8.9). Studies with longer follow up were found to have higher rates of reintervention. The authors note that the medical literature often states that reintervention rates after PUL are around 2-3%, likely due to the fact that they do not include device explant in their data analyses. This study highlights the limitations of studies with short-term follow up and the need comparator trials with long term follow up to determine true rates of reintervention and the burden this has on patients.

- In 2020, Tanneru and colleagues published a meta-analysis and systematic review of intermediate-term follow-up of prostatic urethral lift for benign prostatic hyperplasia.[24] Five studies (totalling 386 patients) with a minimum of 24 months were included in the analysis. After 24 months, mean reduction in International Prostate Symptom Score (IPSS) was 9.1 in the two randomized trials (185 patients) and 10.4 in the 3 nonrandomized studies (201 patients). Quality of life scales improves by 2.2 in an analysis of both randomized and non-randomized trials. The authors noted that there is a paucity of trials investigating PUL with long term follow up, and most available studies have small sample sizes. They concluded that PUL appears to be safe and effective for select patients with BPH, but more studies with longer follow up are needed to determine the permanency of these results.

Randomized Controlled Trials (RCTs)

- The L.I.F.T. study (Luminal Improvement Following Prostatic Tissue Approximation for the Treatment of LUTS secondary to BPH) was a prospective, randomized, controlled, blinded study conducted across 19 centers in the United States, Canada, and Australia.[25] Participants were eligible for inclusion under the following criteria:
    1. >50 years old
    2. IPSS ≥13
    3. Peak flow (Qmax) ≤12 mL/s
    4. Prostate volume 30-80cc
    5. Absence of obstructive median lobe
    6. Absence of active UTI

  A total of 206 participants were enrolled and randomized 2:1 into the treatment (PUL) and sham groups (PUL=140, sham=66). Blinding was done by placement of a surgical screen to block the patient's view and the outcome assessment was completed by someone who was not involved in the original procedure. The sham procedure involved rigid cystoscopy (a procedure to check for any problems in the bladder) with simulated active treatment sounds. PUL participants received anywhere from 2-11 implants. The outcomes of interest were IPSS, QoL, BPH Impact Index, Qmax, sexual function, and adverse events. After the 3 month follow-up, the sham patients were unblinded and offered enrollment into a crossover study where they would receive PUL treatment and be followed for 24 months (Rukstalis et al. study described below).

  The L.I.F.T. RCT is now reporting results on effectiveness, safety, and durability from their 5 year follow-up. The effectiveness of the PUL procedure in regards to IPSS, QoL, BPH Impact Index, and Qmax has been sustained through 5 years. The most significant adverse event reported was encrustation of the implant(s) caused by urine exposure when placed too close to the bladder. Of the 642 implants placed during the L.I.F.T. study, 14 implants (2%) in 10 subjects were encrusted and had to be removed. Other reported adverse events were mild-to-moderate and resolved within 2-4 weeks without treatment. In regards to durability of the UroLift® procedure, 13.6% of the 140 originally enrolled subjects required surgical retreatment. Conversely, additional LUTS treatment after TURP is estimated to be about 6% at 2 years and 8% at 5 years. 17 Sexual function was also evaluated in the L.I.F.T. patients. There were no reports of sexual dysfunction (erectile dysfunction and ejaculatory dysfunction) following the PUL procedure. Also, all patients were able to undergo the procedure under local anesthesia in the urologist's office. The authors attempted to standardize the number of required implants by evaluating prostate size and number of implants placed, but no correlation was found.

  The methodological strengths of this study included recruitment from 19 different health centers across 3 countries, a large sample size based on a power calculation, randomized design, blinding, and comparison to a sham procedure. Analysis was also conducted using the intention-to-treat methodology and patients that experienced protocol deviations or had other prostate-related treatments were censored out of the analysis. Limitations of the L.I.F.T. RCT include the subjective nature of 4 of the 6 outcomes of interest, short follow-up of the sham group (3 months), significant losses to follow-up by year 4, and no comparison to a standard of care surgical BPH treatment (i.e. TURP).

- Sonksen et al. conducted a prospective, multi-center, randomized study to compare PUL to TURP for the treatment of LUTS secondary to BPH.[26] Currently, this is the only head-to-head comparison of PUL using the UroLift® device with the gold standard TURP procedure. Subject eligibility was based on the following criteria:
    1. ≥50 years old
    2. IPSS > 12
    3. Qmax ≤ 15 mL/s
    4. Prostate volume ≤ 60 cc per ultrasound.

  A total of n=80 participants were recruited from 10 different European health centers, randomized 1:1, and followed for 2 years. The primary study endpoint, the BPH6 questionnaire, was specifically designed for this RCT. The BPH6 is a composite of the following 6 other validated questionnaires which assesses overall health:
    1. International Prostate Symptom Score (IPSS)
    2. Sexual Health Inventory for Men (SHIM)
    3. Male Sexual Health Questionnaire for Ejaculatory Dysfunction (MSHQ-EjD)
    4. Incontinence Severity Index
    5. Quality of Recovery Visual Analog Score
    6. Clavien-Dindo classification of adverse events (AEs)

  Secondary endpoints were measures of patient satisfaction, quality of life (QoL), BPH Impact Index, peak flow rate (Qmax), and sleep disturbances.

  Significant improvements were seen in both groups; however, TURP was superior to PUL for improvements in IPSS and Qmax, while PUL was superior to TURP for QoL, quality of recovery, and postoperative sexual function. At the 2 year follow-up, 100% of PUL patients had preserved sexual function while 34% of TURP patients reported ejaculatory dysfunction. TURP patients also experienced a statistically significant worsening of continence function at the 2 week and 3 month follow-up (> 1 point change from baseline for the incontinence severity index (ISI) score) while the PUL patients maintained baseline continence throughout the 2 year follow-up. In regards to 2 year durability of PUL versus TURP, 6 PUL patients (13.6%) and 2 TURP patients (5.7%) required secondary treatment for return of LUTS during the follow-up period.

  Strengths of this RCT included its randomized, controlled design and recruitment from 10 different health centers across Europe. Limitations are due to the small sample size, short follow-up period, and lack of blinding. A significant limitation of this RCT was the use of the BPH6 questionnaire as the primary endpoint. Although the authors stated the questionnaire is based on validated questionnaires, the BPH6 itself has yet to be validated. Using this questionnaire as the primary endpoint of the RCT creates a significant amount of doubt as to the reliability and validity of these results.

<u>Nonrandomized Studies</u>

- Rukstalis et al. evaluated the 2 year effectiveness and durability of PUL in a cross over study of the L.I.F.T. RCT sham patients.[27] Participants were eligible for inclusion under the criteria as the original L.I.F.T. RCT. A total of 51 patients were enrolled in the crossover study, underwent the

PUL procedure, and were followed-up through 24 months. The selected outcomes of interest were IPSS, Qmax, QoL, and BPH Impact Index. The PUL procedure was efficacious for all outcomes through 24 months. Also, sexual function was preserved in all patients with no reported incidences of erectile or ejaculatory dysfunction. The reported adverse events were mild-to-moderate and typically resolved within 2 weeks. Of the 241 devices implanted in the cross over patients, 10 devices (4%) were found to have encrustation due to improper placement and required removal. Also of note, 4 patients (8%) progressed to TURP and 1 patient (2%) required additional PUL implants. Methodological strengths of this study included recruitment out of 19 health centers across 3 countries and the randomized design (from the L.I.F.T. RCT). Limitations included the small sample size and short follow-up period. There were 15 losses to follow-up and no comparison to the gold standard surgical BPH treatment. Also, bias of the results is probable because 3 of the 4 outcome measures were subjective.

- Sievert et al. (2018) evaluated the 2 year effectiveness of Urolift among 86 patients electing the procedure instead of transurethral resection of the prostate (TURP).[28] At 2 years, 86% (n=74) of patients reported statistically significant improvement in symptoms, flow and quality of life. Some patients, 12.8% (n=11), reported persistence of LUTS or remaining PVR, only two of whom elected more implants, one of whom improved while the other did not. Adverse effects were minimal. Limitations include the relatively short follow-up period (2 years); very poor response rate at follow up (47%) and non-randomized study design. Inclusion criteria were also broader than most North American studies, with no exclusions made on the basis of high post-void residual volume (PVR), prostate size, retention history or LUTS oral therapy.

**Transurethral waterjet ablation**

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of transurethral waterjet ablation (e.g., Aquablation) as a treatment for benign prostatic hyperplasia. Below is a summary of the available evidence identified through August 2023.

- In 2021 (reviewed in 2023), Hayes published a health technology assessment of Aquablation for treating BPH. The review included 7 studies, one of which was a randomized controlled trial comparing Aquablation to TURP, and 6 of which were pretest-posttest studies. Effectiveness was assessed through LUTS, QoL, medication usage, sexual function, adverse effects, and reinterventions. Urodynamic testing was used in all 7 trials,[29] finding Aquablation improved Qmax between 9.3ml/sec and 12.9ml/sec. Similarly, 6 studies investigating PVR found reduction after Aquablation treatment. The randomized trial did not statistical differences between TURP and Aquablation patients in Qmax improvement or PVR reduction. The RCT found that IPSS score was statistically noninferior to TURP at 6 months post=operation. The non-comparator studies found improvement in IPSS following Aquablation treatment. Similar results were found for QoL.
  The reviewed studies had several limitations. Only one study had a comparator group, while the others were observational, non-randomized and not blinded. Sample sizes were small, follow-up was limited, and moderate attrition of patient sample. Hayes gave Aquablation a C rating, stating, “This Rating reflects a low quality body of evidence suggesting that Aquablation may improve LUTS associated with BPH at short- to intermediate-term follow-up without impact on sexual function or serious safety issues. This Rating reflects substantial uncertainty due to a lack of comparative evidence consisting of 1 study that demonstrated that Aquablation may be

comparable to transurethral resection, limited long-term evidence regarding the durability and safety of this device, and individual study quality of eligible single-arm studies."[29]

- In 2018 (and updated in 2022), ECRI completed a clinical evidence assessment on AquaBeam Robotic System (Procept BioRobotics Corp.) for treating Benign Prostatic Hyperplasia.[30] This aquablation therapy review included two systematic reviews, one retrospective nonrandomized comparison study, and four pre-/post-treatment studies totally 1,375 patients. One systematic review reported no difference in outcomes between AquaBeam and TURP in symptoms, quality of life (QoL), and retreatment rates at three years. The other systematic review indirectoly compared AquaBeam with Rezūm and Urolift and found reduced lower urinary tract symptoms (LUTS) with AquaBeam at two years. All studies are at moderate to high risk of bias due to one or more of the following: small sample size, high attrition, and lack of randomization, blinding, and control groups. ECRI concluded that AquaBeam is safe and reduces BPH-related LUTS for up to three years. However, the findings need confirmation in additional RCTs to draw firmer conclusions regarding comparative effectiveness. Evidence bar is evidence is somewhat favorable.

- In 2021, Tanneru and colleagues completed a network meta-analysis indirect comparison of newer minimally invasive treatments for benign prostatic hyperplasia.[31] Embase, Medline, and Cochrane databases were searched in December of 2019 for RCTs that reported outcomes after treatment of BPH for prostate size of less than 80 g with Aquablation, Rezūm, or UroLift. A total of four RCTs were identified. Patients that underwent the resective procedures, TURN and Aquablation, had greater improvement in urinary domain outcomes: International Prostate Symptom Score, quality of life, peak flow rate, and postvoiding residual (PVR) compared to patients that underwent non resective procedures: UroLift and Rezūm. UroLift did demonstrate better sexual function domain scores compared to TURP, but not to Aquablation. There was no significant difference in urinary domain scores between UroLift and Rezūm procedures at 24 months of follow-up.

**Transperineal Laser Ablation**

- A 2022 clinical evidence review was published by ECRI Institute on transperineal laser ablation (TPLA) for treating benign prostatic hyperplasia (BPH).[9] The review identified 4 prospective before-and-after studies and 2 retrospective before-and-after studies investigating TPLA in patients with BPH. Sample sizes ranged from 18-160 participants and follow up ranged from 1 to 12 months. International Prostate Symptom Score (IPSS) improved in every study, with 5 of 6 studies showing significant improvement. Sexual function and erectile function varied across studies, with no severe, long-term adverse effects.

  ECRI determined that there are too few data on outcomes of interest to conclude efficacy of TPLA for BPH. "Studies are at a high risk of bias due to two or more of the following: retrospective design, single-center focus, and lack of control groups and randomization. Most studies are small, and none were conducted in the United States; findings may not generalize to patients in the United States. No studies compare TPLA with other minimally invasive BPH treatments or TURP. Large, multicenter RCTs are needed to validate the studies' findings and to compare TPLA with other treatments. Six ongoing trials are likely to address some evidence gaps."[9]

**Temporary Prostatic Urethral Stents**

- In 2023, ECRI published a clinical evidence assessment of the iTind System for treating BPH.[32] The review included 3 systematic reviews, 2 of which were also reviewed by Hayes. The reviews found improvement in prostatic symptoms and QOL with a low complication rate. Only one RCT was included on iTind among the systematic reviews, most studies had limitations such as no active comparator group, small sample size, no randomization or blinding, and short follow up. ECRI concluded that the evidence is inconclusive for the efficacy of iTind to treat BPH due to too few data on outcomes of interest.

- In 2022, Hayes published an evolving evidence review of the iTind system for benign prostatic hyperplasia (BPH).[33] The review included 1 fair-quality RCT comparing iTind to a sham treatment and 2 poor quality pretest-posttest studies. The studies found that iTind may improve lower urinary tract symptoms and quality of life for patients with symptomatic BPH. No studies compared iTind with an alternative active treatment. Hayes also reviewed 3 systematic reviews that suggest a benefit of LUTS relief with iTind. However, evidence from indirect comparisons suggests that iTind may provide less benefit than other minimally invasive treatments. Hayes found the level of support for iTind from clinical trials and systematic review to be minimal due to low quality studies.

**CLINICAL PRACTICE GUIDELINES**

American Urological Association

In 2021, the American Urological Association (AUA) updated an evidence-based clinical practice guideline for the management of lower urinary tract symptoms attributed to benign prostatic hyperplasia (BPH).[34] AUA had the following statement regarding surgical intervention for BPH:

- "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)"
- "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)"

**Water vapor thermal therapy**

American Urological Association

In 2021, the American Urological Association (AUA) updated an evidence-based clinical practice guideline evaluating surgical management of LUTS attributed to BPH.[35] On the basis of grade "C" evidence, the AUA issued a moderate recommendation for water vapor thermal therapy "as a treatment option for patients with LUTS/BPH provided prostate volume 30-80cc."

A conditional recommendation was also given based on Grade C evidence level for water vapor thermal therapy as a treatment for preservation of erectile and ejaculatory function.[35]

National Institute for Health and Care Excellence (NICE)

In 2018, the NICE stated that current evidence on the safety and efficacy of transurethral water vapour ablation for urinary tract symptoms caused by benign prostatic hyperplasia is adequate to support the use of this procedure.[36]

**Urethral Lift**

American Urological Association (AUA)

In 2021, the AUA updated an evidence-based clinical practice guideline addressing the surgical management of lower urinary tract symptoms attributed to benign prostatic hyperplasia.[37] On the basis of grade "C" level evidence, authors issued a "moderate recommendation" supporting the use of prostatic urethral lift in patients with LUTS/BPH, a prostate volume of 30-80cc and the verified absence of an obstructive middle lobe. Authors reviewed the Rukstalis et al. study[38] because of which the FDA expanded indications to allow for patients with an obstructive median lobe. Investigators nonetheless ultimately excluded the study on the grounds that it was "essentially a case series with pre-post outcomes."[37] Authors also recommended that PUL patients be informed that symptom reduction and flow rate improvement is less significant compared to TURP, and that evidence of efficacy and retreatment rates remain "poorly defined."[35]

A "conditional recommendation" was made for PUL in patients concerned with erectile and ejaculatory function for the treatment of LUTS/BPH.

Health Evidence Review Commission (HERC) Oregon

In 2018, HERC published a coverage guidance addressing prostatic urethral lift for the treatment of benign prostatic hypertrophy.[39] On the basis of three studies, investigators issued a "strong recommendation" in support of PUL for the treatment of patients with symptomatic BPH when the following criteria are met:

- Age 50 or older
- Estimated prostate volume <80cc
- IPSS score ≥ 13
- No obstructive median lobe of the prostate identified on cystoscopy at the time of the procedure
- Failure, contraindication, or intolerance to at least three months of conventional medication therapy for benign prostatic hypertrophy

Sexual Medicine Society of North America (SMSNA)

In 2017, the SMSNA released a position statement indicating support for the UroLift® procedure as a treatment of LUTS secondary to BPH. Although this is not an evidence-based clinical practice guideline, authors recognized UroLift® as a treatment option for men with symptomatic BPH due to the available evidence supporting its, "favorable sexual side effect profile over alternative therapies."[40]

National Institute for Health and Care Excellence (NICE)

In 2021, NICE recommend the use of the UroLift® system for treating lower urinary tract symptoms caused by benign prostatic hyperplasia. Investigators recommend the UroLift® system 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."[41]

**Transurethral Waterjet Ablation**

American Urological Association (AUA)

In 2021, the AUA published an evidence-based clinical practice guideline addressing the surgical management of lower urinary tract symptoms attributed to benign prostatic hyperplasia.[37] On the basis of grade "C" level evidence, authors issued a "conditional recommendation" or the use of robotic waterjet treatment for patients with LUTS/BPH provided prostate volume is 30-80cc.

**Temporary Prostatic Urethral Stent**

National Institute for Health and Care Excellence (NICE)

In 2019, NICE stated that current evidence on the safety and efficacy of prostatic urethral temporary implant insertion for [LUTS] caused by BPH is limited in quantity and quality.[42] Therefore, this procedure should only be used in the context of research.

**EVIDENCE SUMMARY**

**Water vapor thermal therapy**

Low-quality but consistent evidence supports the use of Rezūm for the treatment of benign prostatic hyperplasia. Studies to date have consistently reported positive results and low rates of adverse events. The American Urological Association and the National Institute for Health and Care Excellence both endorse water vapor thermotherapy. Results from the largest RCT conducted to date indicate significant improvements in patients' LUTS compared to baseline, although validity was limited by likely attrition bias (primary group: 32.8%, n = 44/134; cross-over group 45.3% n = 24/53). While additional, high-quality RCTs with longer term follow-up and broader inclusion criteria are required to better determine patient selection criteria, Rezūm appears to be at least as safe and effective as comparable treatment options.

**Urethral Lift**

Although current evidence does not support the durability or efficacy of PUL compared to TURP, PUL appears to have significant advantages over TURP due to the less invasive and more convenient nature of the procedure. One of the most notable advantages of the PUL procedure is its ability to significantly preserve sexual and continence function compared to TURP. Additionally, several high-quality clinical practice guidelines conditionally recommend PUL for select patients. Due to the limited number of RCTs comparing PUL to TURP, PUL should not be seen as a replacement for TURP, but rather as an intermediate, minimally invasive option which may prolong the time to a more invasive surgical treatment. While patients typically require 4 implants, patient anatomy varies and some individuals may

require additional implants to durably ensure prostatic de-obstruction. Long-term, high quality prospective studies are needed to confirm the long-term efficacy of the PUL procedure as a treatment for LUTS related to BPH.

**Transurethral Waterjet Ablation**

Low-quality but consistent evidence supports the use of transurethral waterjet ablation for the treatment of benign prostatic hyperplasia. Studies have consistently reported positive results and low rates of adverse events. Additionally, the procedure is noted to have improved urinary function outcomes without (or minimal) impact on sexual function. The American Urological Association also conditionally recommends transurethral waterjet ablation. More long-term, high quality RCTs are needed to draw firmer conclusions regarding comparative effectiveness.

**Not Medically Necessary BPH Treatments**

There is insufficient evidence to support the use of transperineal laser ablation (TPLA) or temporary urethral prostatic stents for the treatment of BPH. More high-quality comparative studies are needed to determine the benefit and safety of the treatments. Furthermore, there are no clinical guidelines with recommendations to support temporary urethral prostatic stents or TPLA. Therefore, transurethral transperineal laser ablation and temporary urethral prostatic stents are considered not medically necessary.

## *BILLING GUIDELINES AND CODING*

| CODES* | | |
|---|---|---|
| **CPT** | 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 | Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance |
| | 53854 | Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy |
| | 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) |
| | 53899 | Unlisted procedure, urinary system |
| **HCPCS** | C2596 | Probe, image-guided, robotic, waterjet ablation |
| | C9739 | Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants |
| | C9740 | Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants |
| | C9769 | Cystourethroscopy, with insertion of temporary prostatic implant/stent with fixation/anchor and incisional struts |

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

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## *POLICY REVISION HISTORY*

| DATE | REVISION SUMMARY |
|---|---|
| 2/2023 | Converted to new policy template. |
| 12/2023 | Annual review. Updated non coverage position from investigational to not medically necessary. Policy title update. |