Medical Policy

Subject:	Surgical and Minimally Invasive Treatments for Benign Prostatic Hyperplasia (BPH) and Other Genitourinary Conditions		
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Description/Scope

This document addresses various surgical and minimally invasive procedures used in the treatment of benign prostatic hyperplasia, and the use of these procedures for other genitourinary conditions. This document does not address the use of open prostatectomy or transurethral resection of the prostate.

Note: Please see the following related documents for additional information:
- MED.00057 MRI Guided High Intensity Focused Ultrasound Ablation for Non-Oncologic Indications
- CG-MED-81 High Intensity Focused Ultrasound (HIFU) for Oncologic Indications
- CG-SURG-61 Cryosurgical Ablation of Solid Tumors Outside the Liver

Position Statement

Medically Necessary:

A. The following surgical procedures are considered **medically necessary** as an alternative to open prostatectomy **or** transurethral resection of the prostate for the treatment of benign prostatic hyperplasia:
   1. Laser-based procedures that have received U.S. Food and Drug Administration approval include, but are not limited to, **any** of the following:
      a. Contact laser ablation of the prostate; **or**
      b. Holmium laser procedures, including Holmium laser ablation of the prostate, Holmium laser enucleation of the prostate, and Holmium laser resection of the prostate; **or**
      c. Interstitial laser coagulation of the prostate; **or**
      d. Photoselective laser vaporization of the prostate; **or**
      e. Transurethral ultrasound guided laser induced prostatectomy; **or**
      f. Visually guided laser ablation of the prostate, also called non-contact laser ablation of the prostate; **or**
   2. Transurethral incision of the prostate; **or**
   3. Transurethral radiofrequency needle ablation, also called transurethral needle ablation; **or**
   4. Transurethral vapor resection of the prostate, also called transurethral electrovaporization of the prostate, transurethral evaporation, or transurethral vaporization of the prostate.

B. The following minimally invasive procedures are considered **medically necessary** as an alternative to open prostatectomy or transurethral resection of the prostate for the treatment of benign prostatic hyperplasia:
   1. Water-induced thermotherapy, also called thermourethral hot-water therapy; **or**
   2. Transurethral microwave thermotherapy; **or**
   3. Prostatic urethral lift in individuals with prostate volume less than 80 mL and image-confirmed absence of an obstructing middle lobe.

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Not Medically Necessary:

Endoscopic balloon dilation of the prostatic urethra is considered **not medically necessary** for the treatment for benign prostatic hyperplasia.

Investigational and Not Medically Necessary:

A. The following procedures are considered **investigational and not medically necessary** for the treatment of benign prostatic hyperplasia:
   1. Cryosurgical ablation; **or**
   2. Prostatic arterial embolization; **or**
   3. Prostatic urethral lift when criteria are not met; **or**
   4. Transurethral convective water vapor thermal ablation.

B. Placement of temporary prostatic stents is considered **investigational and not medically necessary** for **all** indications including, but not limited to, treatment of benign prostatic hyperplasia, following surgical treatment of benign prostatic hyperplasia, prostate cancer, or radiation therapy.

C. The following procedures are considered **investigational and not medically necessary** for all genitourinary conditions **other than** benign prostatic hyperplasia:
   1. Contact laser ablation of the prostate; **or**
   2. Holmium laser procedures of the prostate; **or**
   3. Interstitial laser coagulation of the prostate; **or**
   4. Photoselective laser vaporization of the prostate; **or**
   5. Transurethral microwave thermotherapy; **or**
   6. Transurethral radiofrequency needle ablation, also called transurethral needle ablation; **or**
   7. Transurethral ultrasound guided laser induced prostatectomy; **or**
   8. Visually guided laser ablation of the prostate, also called non-contact laser ablation of the prostate; **or**
   9. Water-induced thermotherapy, also called thermourethral hot-water therapy; **or**
   10. Prostatic urethral lift.

Rationale

Surgical and Minimally Invasive Treatments for Benign Prostatic Hyperplasia (BPH)

Standard surgical treatments for BPH are some of the most common therapies in medical practice. According to the American Urological Association (AUA, 2010), 'gold standard' surgeries include transurethral resection of the prostate (TURP) and, for very large prostate, open prostatectomies. For small prostates (less than 30 gm), the optimal standard option is transurethral incision of the prostate (TUIP). These standard surgeries are typically performed in the operating room setting and require anesthesia, and thus they may be associated with a greater risk for morbidity. Surgical treatments such as open prostatectomy and transurethral resection of the prostate (TURP) may be accompanied by undesirable complications such as blood loss, need for transfusion, and absorption of irrigation fluids. Postoperative side effects may include retrograde ejaculation and incontinence. Surgical techniques have been developed using lasers, as well as minimally invasive techniques using various sources of

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energy including heat, microwaves, radiofrequency, and ultrasound. There are a number of outcome variables to examine in comparing these surgical and minimally invasive treatments to other major surgical procedures.

Laser-based prostatectomy procedures including potassium-titanyl-phosphate photovaporization (Al-Ansari, 2010; Araki, 2008; Elmansy, 2010; Elshal, 2015; Mordasini, 2018; Rusvat, 2008, Stafinski, 2008, Tugcu, 2008) and other surgical and minimally invasive treatments including TUIP (Riehmann, 1995; Tkocz, 2002), transurethral microwave thermotherapy (TUMT), transurethral radiofrequency needle ablation (RFNA)/transurethral needle ablation (TUNA) (Bouza, 2006; Boyle, 2004; Hill, 2004; Hindley, 2001; Roehrborn, 1999), and transurethral vaporization of the prostate (TUVP) (Ekengren, 2000; Poulakis, 2004; Van Melick, 2002; Van Melick, 2003) have been established as useful and alternative procedures to TURP.

Holmium laser procedures including Holmium laser ablation of the prostate (HoLAP) (Elmansy, 2010), Holmium laser enucleation of the prostate (HoLEP) (Ahyai, 2007; Elzayat, 2007; Kuntz, 2008; Shah, 2007; Tan, 2007; Wilson, 2006) and Holmium laser resection of the prostate (HoLRP) (Ruzat, 2008; Westenberg, 2004) have been evaluated in clinical trials and compared with TURP in meta-analyses and systematic reviews. The data in the peer-reviewed medical literature suggests that these procedures may provide improvement in BPH symptoms, voiding function, and urinary retention, in addition to comparing favorably in the long-term to TURP with equally low complication rates.

Although there is a lack of data directly comparing water-induced thermotherapy (WIT) with either TURP or other surgical procedures, the safety and efficacy of WIT has been shown to relieve the symptoms of BPH without the occurrence of blood loss, incontinence, and impotence which are sometimes associated with TURP (Breda, 2002; Muschter, 2000).

TUMT (CoreTherm®, Prostalund® AB, Uppsala, Sweden; Prolieve Thermodilatation® System, Boston Scientific Corp. U.S.A, Natick, MA; Prostatron® and Targis® Systems, Cooled ThermoTherapy™, Urologix®, Minneapolis, MN; TMx-2000™ TherMatrx®, American Medical Systems, Inc., Minnetonka, MN) is an alternative treatment to TURP for BPH (Albala, 2002; Dahlstrand, 1995; Wagrell, 2004). Several randomized controlled and non-randomized comparative trials have demonstrated that TUMT has similar efficacy as TURP in symptom relief and satisfaction (Albala, 2002; Floratos, 2001; Hoffman, 2012; Kaye, 2008; Miller, 2003; Mynderse, 2011; Norby, 2002; Ohigashi, 2007; Vesely, 2005).

Other Minimally Invasive Treatments for BPH

Prostatic Arterial Embolization (PAE)

PAE has been proposed as a treatment for BPH to reduce the blood supply of the prostate gland which results in some of the gland undergoing necrosis with subsequent shrinkage. The procedure is performed with the individual under local anesthetic using a percutaneous transfemoral approach. Embolization is achieved using microparticles (such as gelatin sponge, polyvinyl alcohol [PVA], and other synthetic biocompatible materials) introduced by super-selective catheterization to block small prostatic arteries. In June 2017, the U.S. FDA granted a de novo classification to the intravascular implant, Embosphere Microspheres (BioSphere Medical, S.A., France), as a class II biocompatible PAE device for use as a minimally invasive treatment for symptomatic BPH.

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The published literature on PAE has been summarized in systematic reviews and meta-analyses (Jiang, 2019; Malling, 2019; Shim, 2017). Malling (2019) reviewed controlled and uncontrolled studies on PAE for BPH that had at least 10 participants and at least 6 months of follow-up. A total of 13 studies met the review's eligibility criteria, including 2 randomized controlled trials (RCTs). One RCT (Carnevale, 2016) had only 2 participants and the other (Gao, 2014) included 114 individuals. The primary outcome of interest was mean change in the International Prostate Symptom Score (IPSS). In a pooled analysis of symptom improvement at 12 months among individuals receiving PAE, the mean reduction (indicating symptom improvement) in IPSS was -16.2 points (95% confidence interval [CI], -18.3 to -14.0). Secondary outcomes, including quality of life and prostate volume, also improved after PAE. The meta-analysis is limited by lack of comparative analysis and the literature on PAE is limited by the small number of comparative studies.

The meta-analysis by Jiang (2019) focused on studies comparing PAE to TURP and evaluated short-term outcomes. Four studies were included in the review, the 2 RCTs mentioned above as well as 2 comparative observational studies. In a pooled analysis of data from 2 studies, there was no significant difference in post-operative IPSS. The post-operative peak flow rate (Qmax) was significantly higher in the TURP group than the PAE group. Similarly, the post-operative prostate volume and quality of life improved significantly more in the TURP group. Data from 2 studies found no statistically significant differences in complications in the 2 groups.

The RCT by Gao (2014) included individuals with lower urinary tract symptoms (LUTS) due to BPH who had an IPSS score greater than 7, a prostate volume of 20-100 mL and peak urinary flow of less than 15 mL per second. A total of 114 individuals met the eligibility criteria and were randomized to PAE (n=57) or TURP (n=57). Participants were followed for a mean of 22.4 months. Efficacy outcomes included IPSS, quality of life, peak urinary flow and post-voiding residual urine volume. At the 1- and 3-month follow-ups, there was significantly greater improvement in these outcomes in the TURP group. At all time-points, there was significantly greater reduction in prostate volume in the TURP group. A significantly higher percentage of individuals in the PAE group had complications; most of these were minor complications. In the PAE group, there were 22 (38.6%) minor complications and 8 (14%) major complications whereas in the TURP group, there were 13 (22.8%) minor complications and 4 (7%) major complications. Technical and clinical treatment failure were included in the calculation of major complication.

A randomized non-inferiority trial was published by Abt and colleagues in 2018. The study included 103 individuals with refractory LUTS due to BPH who were randomized to undergo PAE (n=48) or TURP (n=51). Non-inferiority for the primary outcome was defined as less than a 3 point difference in IPSS improvement at 12 weeks. From baseline to 12 weeks, change in the IPSS was -9.23 pints after PAE and -10.77 after TURP. Thus, non-inferiority of PAE to TURP was not established. Functional outcomes at 12 weeks favored the TURP group. The risk of one or more treatment-related adverse events was similar in the 2 groups but more individuals in the TURP group had 2 or more treatment-related adverse events.

There are a number of uncontrolled studies evaluating PAE for treatment of BPH. One of the larger series was published by Pisco and colleagues in 2016. A total of 630 individuals with BPH and moderate to severe LUTS refractory to medical therapy for at least 6 months or who refused any medical therapy underwent PAE. Outcomes were evaluated at baseline, 1, 3, and 6 months; every 6 months between 1 and 3 years; and, yearly thereafter up to 6.5 years. The mean participant age was 65.1 years ± 8.0 (range, 40-89 years). There were 12 (1.9%) technical failures with the procedure. Bilateral PAE was performed in 572 (92.6%) participants and unilateral PAE was

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performed in 46 (7.4%) participants. A total of 10 of 58 participants who underwent repeat PAE were lost to follow-up before any data could be obtained. There was a statistically significant change from baseline to last observed value reported in all clinical parameters including IPSS, quality of life, post-void residual urine volume (PVR), PSA, Qmax, and IIER, defined as clinical success rates of 81.9% and 76.3% at medium- (1-3 year) and long-term (> 3-6.5 years) follow-up, respectively ($p<0.0001$). There was one PAE-related major adverse event, a case of bladder wall ischemia treated by simple surgery, and another participant experienced uncomfortable perineal pain lasting for 3 months. Limitations of this study include the nonrandomized study design and lack of a control group of participants treated with other BPH therapies for comparison.

PAE for symptomatic BPH has been assessed in a number of case series and single-center studies, mainly with small sample sizes. These studies evaluated measures of clinical symptom improvement (Bagla, 2014; Carneval, 2013; Grosso, 2015; Pisco, 2013; Rio Tinto, 2012; Wang, 2016), laboratory and urodynamic findings (Antunes, 2013), use of different PVA particle sizes (Bilhim, 2013a), clinical outcomes comparing unilateral to bilateral PAE (Bilhim, 2013b), and quality of life measures. Few post-PAE complications were reported in these studies, including urinary tract infection requiring antibiotics and acute post-PAE urinary retention requiring temporary catheterization.

Other Considerations

The 2018 AUA guideline on *Surgical Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia* (2018) does not recommend PAE "…for the treatment of LUTS attributed to BPH outside the context of a clinical trial (Expert Opinion)."

A Society of Interventional Radiology (SIR) (McWilliams, 2014) position statement for use of prostate artery embolization for the treatment of benign disease of the prostate states:

> Although there maybe emergency indications for PAE for post-operative bleeding or other urgent indications, elective PAE for BPH requires additional investigation before its acceptance into routine therapy. Additional studies, some of which are ongoing, should investigate midterm and long-term efficacy of the procedure, including subjective symptom scores and objective measures such as peak flow rate, prostate volume, and post void residual volume. Prospective, randomized comparison versus TURP and other surgical therapies will help delineate the role of PAE among the many treatment options for LUTS. Safety of the procedure should continue to be verified by tracking and reporting of adverse events.

In summary, most studies evaluating PAE for the treatment of LUTS secondary to BPH lack a control group, have a degree of variation in the reported rates of symptom improvement, and lack comparisons to standard therapies such as TURP or open prostatectomy. Additional well-designed randomized controlled trials are needed to determine the net health benefit of PAE compared to other procedures in the treatment of LUTS secondary to BPH.

Prostatic Urethral Lift (PUL) System

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The PUL system is a minimally invasive treatment for symptomatic LUTS secondary to BPH. The procedure is performed by transurethral delivery of small PUL implants to secure the prostatic lobes in an open position, thereby reducing the obstruction of the urethral lumen.

The NeoTract UroLift® System (NeoTract Inc., Pleasanton, CA) received FDA 510(k) designation (K130651) on September 13, 2013 as a de novo device indicated for the treatment of men 50 years of age and older with LUTS secondary to BPH. The FDA noted that UroLift should not be used in the following situations:

- Prostate volume of > 80 cc
- An obstructive or protruding median lobe of the prostate
- A urinary tract infection
- Urethra conditions that may prevent insertion of delivery system into bladder
- Urinary incontinence
- Current gross hematuria
- A known allergy to nickel

L.I.F.T Study

Roehrborn and colleagues (2013) reported initial results of the multicenter crossover randomized trial of the UroLift System for the treatment of LUTS secondary to BPH known as L.I.F.T. The trial included men ages 50 and older with a prostate size of 30 to 80 cubic centimeters, AUA Symptom Index (AUASI) 13 or greater and maximum flow rate 12 milliliters per second or less. Median lobe obstruction was one of the exclusion criteria. The 2-phase study included a randomized single-blinded period, starting at the time of the procedure and ending at the participant's 3-month visit, followed by a nonrandomized open-label period. After the 3-month follow-up visit, participants were unblinded to treatment group. If symptoms returned and treatment was required, participants were allowed to receive treatment with the UroLift System or any other approved BPH treatment.

A total of 206 men were randomized 2:1 between PUL device (n=140) or sham treatment (n=66). The primary efficacy endpoint (intention-to-treat [ITT]) was demonstration of a reduction in AUASI at least 25% greater than that of sham treatment at 3 months post-PUL procedure. All participants in the PUL group were followed through 1 year to evaluate durability of effect. Secondary effectiveness endpoints included measurements in Qmax at 3 and 12 months, IPSS at 2 weeks, and quality of life and BPH-II at 12 months. The primary safety endpoint was to demonstrate an observed rate of ≤ 10% postoperative urinary catheterization for more than 7 days. After the 3-month endpoint, 53 of 66 participants in the sham treatment group elected to undergo the PUL procedure. Follow-up outcomes for those individuals were not reported in this article. At 12 months, 123 participants were included in the analysis: 1 participant dropped out, 2 were excluded due to significant protocol deviations, 5 participants elected to undergo PUL revision because of insufficient response, 2 participants elected prostate resection, and 7 participants were removed due to BPH medication use.

The primary study endpoint was met, as the mean PUL and sham AUASI was reduced by 11.1 (± 7.67) and 5.9 (± 7.66), respectively (p=0.003). PUL participants experienced AUASI reduction from 22.1 baseline to 18.0, 11.0 and 11.1 at 2 weeks, 3 months and 12 months, respectively (p<0.001). Qmax improvement increased 4.4 milliliters per second at 3 months and was sustained at 4.0 milliliters per second at 12 months (p<0.001). There was no statistical difference between groups in International Index Erectile Function (IIEF). Two serious adverse events were

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determined as related to the procedure (clot retention coincident with reinitiating warfarin therapy and removal of a bladder stone at 12 months). Less serious adverse events, including postoperative dysuria, hematuria, pain/discomfort and urgency were typically mild to moderate and resolved within 2 weeks. Limitations of this study include the lack of blinding and absence of a comparator treatment group beyond the primary study endpoint follow-up visit. The rate of blinding for participants was reported at 57% at the 3-month follow-up. Of the 140 participants in the treatment arm, 20% (17 participants) were excluded in the final analysis (unblinded phase) at 12 months.

Cantwell and colleagues (2014) reported outcomes from participants who received sham treatment during the L.I.F.T. trial. A total of 53 participants who crossed over and were unblinded to treatment at 3 months elected to undergo PUL. At 12 months after PUL and with each participant serving as his own control, the clinical effects of PUL associated with early symptom relief, low morbidity and preservation of sexual function corroborated findings in the randomized L.I.F.T. trial; however, as the study was unblinded, the possibility of a placebo effect cannot be excluded. In addition, the durability of PUL was not evaluated beyond 1 year.

Three-year results of the L.I.F.T. study were reported by Roehrborn and colleagues in 2015. A total of 129 of 140 (92.1%) participants were followed for 3 years (n=11, lost to follow-up) and assessed for LUTS severity (IPSS), quality of life, peak flow rate, sexual function, and adverse events. To evaluate per protocol change from baseline, the authors used a general estimating equation (GEE) model for each output parameter to calculate *p* values for each follow-up interval compared to baseline. Change from baseline was the dependent variable; visit and baseline score were used as independent variables. A total of 93 of the original cohort of 140 (66.4%) participants (that is, participants allocated to PUL and included in the ITT analysis performed at 3 months) were included in the 3-year effectiveness analysis. Of the 36 participants excluded, 13 participants had used alpha-blocker or 5-alpha reductase inhibitors, 3 participants had missing data, 3 participants deviated from the study protocol, and 2 participants had an unrelated prostate procedure. For the remaining 15 participants (of the original 140 participants randomized to PUL [10.7%]), 6 men received additional PUL implants and 9 men required surgical intervention with TURP or laser vaporization for treatment failure; however, the authors state "this rate is similar to rates reported after TURP (2.3-4.3% at 1 year, 5.8%-9.7% at 5 years) and laser vaporization (1.7%-5.3% at 1 year, 6.7% at 2 years, 6.8%-34% at 5 years)."

The therapeutic effects of PUL, reported as average improvements from baseline through 3 years, were significant for total IPSS (41.1%), quality of life (48.8%), peak flow rate score (53.1%), and individual IPSS symptoms ($p<0.0001$ [GEE], respectively). For PUL participants, sexual function was preserved with no reported adverse events or de novo sustained erectile or ejaculatory dysfunction. Concerning the latter, the authors state "most medications and all of the invasive options for the management of benign prostatic obstruction (BPO) have been shown to have a negative impact on ejaculatory function." In addition, "prostate volume, prostate length, number of placed implants, and the density of placed implants are not correlated with symptom relief and do not appear to predict response to the procedure." Despite the lack of direct comparison data, the authors state the results of this study "suggest that the overall secondary procedure rate after PUL would be considerably less than after TUMT (31%-40% at 3 years) and TUNA (20%-36% at 2-3 years)." Limitations of this analysis include the methodological use of a GEE (estimation) model for each parameter to correlate data from baseline to 3 years for repeated study measures. This methodology may result in underestimation of errors unless the sample size is very large. In addition, ITT analysis of data was performed at 3 months but not at the 3-year follow-up, as only 93 of the 140 (66.4%) PUL-treated participants were included in the final "per protocol" analysis.

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Roehrborn and colleagues (2017a) reported 5-year results from the L.I.F.T. trial. Participants who underwent an additional BPH procedure, were taking a BPH medication, or deviated from study protocol were excluded from the per protocol (PP) analysis; for participants in the ITT analysis, the last value prior to study exclusion was carried forward. The ITT and PP analysis results were reported as "durable" through 5 years in IPSS (ITT, 35%; PP, 36%), quality of life (ITT, 44%; PP, 50%), BPH-II (ITT, 47%; PP, 52%), and Qmax (ITT, 50%; PP, 44%). For 72 (51.4%) of 140 participants included in the PP analysis, change in IPSS score from baseline to 5 years was -7.56 or -35.9% (95% CI, -44.4% to -27.3%; p<0.0001). For the 140 participants included in the ITT analysis, change in IPSS score from baseline to 5 years was -7.85 or -35.0% (95% CI, -41.0 to -29.0%; p<0.0001). There was no significant difference in any efficacy measures between the PP and ITT analysis. Of the 140 originally randomized participants, data were available for 104 (74.3%) participants at 5 years of follow-up. Of the 36 not available, 18 (12.9%) participants were lost to follow-up, 9 (6.4%) died of unrelated causes, and 9 (6.4%) participants exited the study for either treatment of unrelated cancer (n=5) or after undergoing TURP (n=4). A total of 19 (13.6%) participants were surgically retreated for "failure to cure" following PUL at 5 years: 6 (4.3%) received additional PUL implants and 13 (9.3%) participants were treated with TURP or laser ablation (including 4 participants that exited the study). There was one adverse event occurring in 1 participant over the time period of 49 to 60 months (hematuria). Sexual function was stable over 5 years with no de novo, sustained erectile or ejaculatory dysfunction.

BPH6 Study

Sonksen and colleagues (2015) reported on the 12-month results of the BPH6 study, a multicenter RCT comparing PUL (n=45) to TURP (n=35) in 80 participants 50 years of age and older who were candidates for TURP. After randomization (n=91), 10 individuals (10.9%) allocated to TURP and 1 individual (1%) allocated to PUL withdrew from the study, declining the index treatment. The primary study endpoint assessed a composite of six elements (that is, symptom relief, quality of recovery, erectile function preservation, ejaculatory function preservation, continence preservation, and safety) with the overall objective of showing noninferiority of PUL to TURP for the composite endpoint at 12 months. Noninferiority was evaluated using a 1-sided lower 95% CI for the difference between PUL and TURP performance.

The proportion of participants who met the BPH6 primary endpoint was 34.9% for the PUL group and 8.6% for the TURP group (noninferiority, p=0.0002; superiority, p=0.006). After adjusting for differences in baseline parameters between the enrollment arms, the refined BPH6 primary endpoint was also met by 52.3% of PUL participants and 20.0% of TURP participants (noninferiority, p<0.0001; superiority, p=0.005). The reintervention rate for treatment failure was 6.8% (3 of 44) of PUL participants and 5.7% (2 of 35) TURP participants. Two participants in the TURP group required surgical intervention for adverse events; in addition, PUL participants experienced fewer treatment-related infections (7%) than TURP participants (14%) (p=0.46). In the final analysis, the PUL procedure met the primary study endpoint of noninferiority and demonstrated superiority in the BPH6 primary endpoint; however, TURP was superior in reducing IPSS reduction goal of ≥ 30% (73% vs. 91%; p=0.05) where PUL was superior for quality of recovery (p=0.008) and preservation of ejaculatory function (p<0.0001). Limitations of this study include the short-term follow-up of 1 year and the study sample size, which was insufficiently powered to detect meaningful differences in secondary endpoints.

Gratzke and colleagues (2017) reported on 2-year participant-centered and quality of life assessment outcomes of the BPH6 trial (n=45 PUL participants; n=35 TURP participants) following PUL for symptomatic BPH. At the 24-

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month follow-up, the mean difference (change) in IPSS between PUL and TURP favored TURP (6.1; standard deviation, -9.2 to -15.3, respectively; p<0.001). Subjective outcomes of participant-reported quality of life were similar between PUL (n=45) and TURP (n=35) participants at all follow-up intervals. TURP was superior with regard to Qmax scores at all study time points, while changes in health-related quality of life and BPH-II improvements were not statistically different; changes in prostate volume were not reported. Ejaculatory function bother scores did not change significantly in either treatment arm while PUL resulted in statistically significant improvement in sleep. Reoperation rates due to symptom recurrence among PUL and TURP participants did not differ significantly over the 2-year study. Six participants in the PUL arm (13.6%) and 2 participants in the TURP arm (5.7%) underwent secondary treatment for return of LUTS. The participant-reported incidence for incontinence (incontinence severity index [ISI]) change from baseline over time was statistically significant at 2 weeks and 3 months following TURP compared with PUL; however, the change over time was statistically insignificant after 6 months through 24 months of follow-up. Limitations of this study include the small sample size which may have resulted in insufficient statistical power to detect differences in some outcomes. Another study limitation includes use of the BPH6 composite endpoint, as it is not a validated study instrument, despite being composed of individually validated instruments.

Several systematic reviews and meta-analyses have been published (Jones, 2016; Perera, 2014). Most recently, Jones and colleagues (2016) reviewed UroLift studies with at least 12 months of follow-up. A total of seven studies were identified, which included four non-comparative studies (Bozkurt, 2016; Chin, 2012; McNicholas, 2013; Woo, 2012), one crossover study (Cantwell, 2014), and two RCTs (Roehrborn, 2013; Sonksen, 2015). The review included data from 440 subjects; however, only data were included from men in the UroLift arms of the randomized controlled trials. Summaries were created from the combined study results, but the methods used to combine the data for meta-analysis were not described and precision estimates were not given. The authors reported that mean Qmax increased from 8.4 mL/s to 11.8 mL/s, mean IPSS improved from 24.1 to 14, mean quality of life improved from 4.5 to 2.3, and mean 5-item IIEF score improved from 17.7 to 18.2. The most frequent complications reported were dysuria, hematuria and pelvic pain.

Additional non-controlled studies have been published (Shah, 2018; Sievert, 2018). The Shah study found similar efficacy in men with larger (> 80 g, n=23) and smaller (< 80 g, n=51) prostates. In the Sievert study, TURP candidates were given the choice of undergoing PUL. A total of 86 individuals chose PUL, including 38 with severe BPH obstruction who would have been excluded from other studies. Within 1 month, 74 participants (86%) reported substantial improvement in symptoms. These studies are limited by the lack of a comparison or control group and lack of long-term follow-up.

Other Considerations for PUL for BPH

The 2018 AUA guideline on the *Surgical Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia* includes the following recommendations for use of PUL for LUTS attributed to BPH:

> 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; however, patients should be informed that symptom reduction and flow rate improvement is less significant compared to TURP (Moderate Recommendation; Evidence Level: Grade C).

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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).

Temporary Prostatic Stents

The use of temporary prostatic stents has been proposed as treatment of urinary obstruction due to BPH, following surgical treatment of BPH or prostate cancer, or following radiation therapy. Intra-prostatic stenting has been investigated as a short-term treatment option permitting voluntary urination as an alternative to an indwelling bladder catheter with an external collection system. A temporary prostatic stent, The Spanner™ (SRS Medical, North Billerica, MA), received premarket approval (PMA) from the FDA based on a multicenter, prospective, randomized clinical trial designed to evaluate the safety and effectiveness of The Spanner to manage LUTS and bladder emptying following TUMT treatment after an initial period of catheterization. Based on the study results, the FDA indicates "The device is intended for temporary use (up to 30 days) to maintain urine flow and allow voluntary urination in patients following minimally invasive treatment for benign prostatic hyperplasia (BPH) and after initial post-treatment catheterization."

An RCT evaluating The Spanner (Dineen, 2008; Shore, 2007) included 186 male subjects who were, 45 years of age and older. Participants were randomized into 2 groups at a visit 3 to 10 days following TUMT for BPH, indwelling bladder catheter removal, and demonstration of a successful voiding trial (defined as a PVR less than 250 milliliters with mean voided volume of at least 100 milliliters). A total of 100 subjects who received The Spanner and 86 subjects in the control group were studied for changes in IPSS, PVR, and adverse events. Both groups were evaluated at 1-, 2-, and 4-week intervals during The Spanner indwelling period and at 2 and 4 weeks after The Spanner removal. Beginning with preoperative IPSS scores of approximately 22 points, The Spanner group score decreased by 7.28 points compared to 4.42 points in the control group, a difference of 2.86 points (p=0.019). However, although evaluation at the 1-week interval revealed a significant difference of 3 points between the groups (p=0.047), at 2 weeks and at subsequent visits, this was no longer the case (p=0.084 at 2 weeks). Mean PVR was significantly less in The Spanner group compared to controls up to 4 weeks following randomization, with the mean decrease from pre-insertion baseline being 6.5 mls in The Spanner group versus a 28.5 ml increase in the control group. However, after 4 weeks there was no significant difference in PVR between the groups. The most notable limitation of this study is the lack of long-term follow-up, as uroflowmetry, PVR, and IPSS data was only collected up to 1 week following stent removal; therefore, the durability of the results are not evident.

The FDA summary reported the majority of adverse events, greater than 75% for both groups, occurred during weeks 1 to 4 following insertion. Adverse events also occurred following removal of the device and included bleeding/hematuria, urinary frequency/retention/urgency, perineal pain, and symptomatic urinary tract infection. There were 385 adverse events reported by 99 subjects in The Spanner group and 273 adverse events reported by the 80 control group subjects. Of the urological adverse events requiring treatment, bacturemia occurred in 16.0% of The Spanner group compared to 10.5% in the control group. Micturition-burning was noted in 9.0% and 5.8%; perineal pain in 5.0% and 2.3%, respectively. However, the overall incidence of perineal pain was 26% in The Spanner group compared to 12.8% in the control group. Urinary retention (undefined) occurred in 10% and 15.1%, respectively. In The Spanner group, 2 of these occurred after removal of the temporary stent and 3% were associated with migration. The study results are limited in demonstrating meaningful improvement in clinical outcomes in the group that received the temporary prostatic stent compared to the subjects studied who had a

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successful voiding trial after BPH surgery. The clinical significance of decreased IPSS scores at 1 week only with a difference of 3 points at that visit is questionable as is the difference in PVR noted up to 4 weeks, in the absence of increased urinary tract infections or other PVR-related adverse effects in the control group compared to The Spanner group. On the other hand, perineal pain was noted to occur more frequently in The Spanner treated group.

In a case series, Grimsley and colleagues (2007) retrospectively reviewed data on 43 consecutive individuals who were treated with The Spanner for bladder outlet obstruction because they were unfit for surgery (for example, comorbidity, usually pulmonary, cardiac, or both). Six (14%) of the individuals were receiving concomitant treatment for prostate cancer. It was reported that more than half of the individuals (63%) had unsatisfactory outcomes; the remaining 37% were considered to have had satisfactory outcomes with a stent in-situ after a mean of five changes or stent-free after a successful voiding trial. The authors suggest that, in this population, a temporary stent might be reasonably used only as a trial for placement of a permanent stent if voiding is unsuccessful.

In summary, the peer-reviewed medical literature regarding use of temporary prostatic stents for the treatment of urinary obstruction due to BPH and other genitourinary conditions (such as bladder outlet obstruction) consists primarily of small case series, retrospective studies (Roach, 2017), analysis of a BPH database (Tyson, 2012), and review articles. Additional study is needed to determine if use of temporary prostatic stents will result in clinically significant improvement in urinary function and symptom control with less adverse effects, especially in individuals who may be unfit for surgical intervention for BPH or other genitourinary conditions.

Transurethral Convective Water Vapor Thermal Ablation

Transurethral convective water vapor thermal ablation therapy is being evaluated as a treatment for LUTS due to BPH. The Rezūm System (NxThera, Inc., Maple Grove, MN) received FDA 510(k) designation (K150786) on August 27, 2015 as a sterile water vapor (103ºC) system to treat BPH by delivering targeted, controlled doses of stored thermal energy (created with radiofrequency current) directly to the transition zone of the prostate gland. A narrow sheath, similar in shape and size to a cystoscope, is inserted transurethrally and positioned within the prostatic urethra between the bladder neck and the verumontanum. A thin needle is positioned through the urethra into the transition zone, and a short (8-10 second) delivery of water vapor is injected directly into the hyperplastic tissue, retracted, and then repositioned to additional treatment sites as needed. Upon contact with the tissue, the vapor condenses into its liquid state, releasing the stored thermal energy contained within the vapor. This thermal energy is released directly against the walls of the tissue cells within the treatment zone. The treatment can be customized to the shape and location of the gland including the median lobe.

McVary and colleagues (2016a; 2016b) reported outcomes from a multicenter RCT using transurethral prostate convective water vapor thermal energy to treat LUTS associated with BPH. A total of 197 men aged 50 years or older with an IPSS of 13 or greater, maximum flow rate of 15 ml per second or less, and prostate size 30 cc to 80 cc were randomized 2:1 between thermal therapy with the Rezum System (n=136) and control (n=61). Thermal water vapor was injected into the transition zone and median lobe as needed. The control procedure was rigid cystoscopy with simulated active treatment sounds. The primary endpoint was a blinded comparison of reduction in IPSS at 3 months. Participants in the Rezum group continued to be followed until 12 months after treatment. Thermal therapy and control IPSS was reported as reduced by 11.2 ± 7.6 and 4.3 ± 6.9, respectively ($p<0.0001$). Participants in the Rezum group had an IPSS reduction of 22 points from baseline at 2 weeks ($p=0.0006$) post-

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treatment and by 50% or greater at 3, 6 and 12 months (p<0.0001). The peak flow rate increased by 6.2 ml per second at 3 months and was sustained throughout 12 months (p<0.0001). Adverse events were reported as mild to moderate and resolved quickly.

In a subset analysis, McVary and colleagues (2016a) evaluated participant satisfaction rates in erectile and ejaculatory function post-treatment with the Rezum System. The minimal clinically important difference in erectile function perceived by participants as beneficial was determined for each erectile function severity category. No treatment- or device-related de novo erectile dysfunction occurred after Rezum therapy. Ejaculatory bother score improved 31% over baseline (p=0.0011). A total of 32% of participants achieved minimal clinically important differences in erectile function scores at 3 months, and 27% at 1 year, including those with moderate to severe erectile dysfunction. While convective water vapor thermal therapy provided sustained improvements for 12 months in LUTS and urinary flow while preserving erectile and ejaculatory function, some limitations in the study design and subset analysis are apparent. There were no direct comparisons of convective water vapor thermal therapy with other minimally invasive treatments for LUTS associated with BPH. The study design did not account for confounding factors, such as the existence of other medical conditions in the sample population, including, but not limited to, androgen deficiency, metabolic syndrome, and lifestyle factors.

Roehrborn and colleagues (2017b) reported 2-year outcomes of the McVary plus 1-year results of a crossover trial after transurethral prostate convective water vapor thermal energy treatment with Rezum to treat LUTS associated with BPH. After unblinding at 3 months, 53 of 61 (86.9%) control group participants who met IPSS and Qmax criteria elected and requalified for crossover to active treatment. Crossover study participants were assessed per protocol at 3 months (n=50), 6 months (n=49), and 12 months (n=45, 84.9%). Per protocol participants were assessed at 3, 6, 12 and 24 months after treatment with Rezum. The primary efficacy endpoint was a change in IPSS at 24 months. At 3 months (n=134), 6 months (n-129), and 12 months (n=121), per protocol participants treated with Rezum reported a significant improvement over controls in IPSS and a sustained reduction from baseline to 24 months (n=106 [80.7%] participants) (-51% change; 95% CI, -57 to -45; p<0.0001). Crossover participants experienced improvement in IPSS (p=0.004), Qmax (p<0.0001), and quality of life (p=0.0024) measures after Rezum therapy compared to after the control procedure. During the 24-month follow-up, 8 participants received secondary treatment, including open prostatectomy (n=1), a second Rezum procedure (n=3), and TURP (n=4). A total of 9 participants withdrew from the study and 2 participants in the crossover group experienced a total of 3 serious procedure-related adverse events (bladder neck contracture, bladder calculi, and urosepsis). The most common mild to moderate adverse events were dysuria (18.9%) and hematuria (11.3%). The investigators reported that preservation of sexual function in Rezum-treated participants was sustained in participants after the crossover procedure and throughout the 2-year follow-up.

McVary and colleagues (2019) reported outcomes up to 4-years in the Rezum-treated group from the RCT. (Blinded comparison with the control group was only available after 3 months). Of the original 135 participants in the Rezum group at baseline, 99 (73%) had follow-up data at 3 years and 89 (66%) at 4 years. Among available participants, mean IPSS, which had been reduced by 49.9% at 3 months, was reduced by 49.7% at year 3 and 46.7% at year 4. Symptom scores also continued to be improved compared with baseline up to 4 years. No late adverse event or *de novo* erectile dysfunction were reported.

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In summary, additional longer-term data are needed from larger randomized, comparative studies to determine the net health benefit of convective water vapor thermal therapy compared to standard treatments for LUTS associated with BPH.

Other Considerations for Transurethral Convection Water Vapor Thermal Therapy for BPH

The 2018 AUA guideline on *Surgical Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia* includes the following recommendations for use of water vapor thermal therapy for LUTS attributed to BPH:

> Water vapor thermal therapy may be offered to patients with LUTS attributed to BPH provided prostate volume <80 g; however, patients should be informed that evidence of efficacy, including longer-term retreatment rates, remains limited (Conditional Recommendation; Evidence Level: Grade C).
>
> Water vapor thermal therapy may be offered to eligible patients who desire preservation of erectile and ejaculatory function (Conditional Recommendation; Evidence Level: Grade C).

Other Treatments for BPH

The earlier AUA's *Guideline on the Management of Benign Prostatic Hyperplasia (BPH)* (AUA, 2010) excludes a number of procedures from consideration in their treatment outcome analysis as there is insufficient and inadequate evidence available to make a recommendation for these procedures as a treatment alternative for an individual with moderate to severe symptoms of BPH. The level of evidence regarding the safety and utility of endoscopic balloon dilation, cryosurgical ablation, and the placement of stents, including a lack of treatment outcome analysis for temporary prostatic stents, is insufficient to draw any conclusions. Further studies are needed before determining the role of these treatments in the routine management of men with BPH.

Endoscopic balloon dilation for treatment of BPH involves the insertion of a balloon catheter tip through the urethra into the prostatic channel where it is inflated to stretch the urethra narrowed by the prostate. Based on the research, endoscopic balloon dilation has been inadequately studied with limited controlled trials, few long-term studies, and "a fallout in enthusiasm" for this treatment (Lukkarinen, 1999). The 4th International Consultation on BPH has rated balloon dilation as an unacceptable treatment option since 1995 (Denis, 1998).

Surgical and Minimally Invasive Treatments for Genitourinary Conditions Other Than BPH

The efficacy of surgical and minimally invasive procedures including contact laser ablation of the prostate (CLAP), holmium laser procedures, interstitial laser coagulation of the prostate (ILCP), PVP, RFNA/TUNA, transurethral ultrasound guided laser induced prostatectomy (TULIP), TUMT, visually guided laser ablation of the prostate (VLAP), and WIT has not been established as treatment for prostatic or other genitourinary conditions other than BPH. The AUA, American Society for Radiation Oncology (ASTRO), and the Society for Urologic Oncology's (SUO) *Guideline for the Management of Clinically Localized Prostate Cancer* (AUA, 2017), the National Cancer Institute's Prostate Cancer Treatment (PDQ®) (NCI, 2017), and the National Comprehensive Cancer Network® (NCCN) Clinical Practice Guidelines in Oncology-Prostate Cancer (V1.2019) do not address

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these procedures as a treatment option for prostate carcinoma and related conditions. The level of evidence supporting the use of the technologies mentioned for conditions other than BPH is insufficient to draw conclusions regarding safety and efficacy. Further studies are needed before they can be considered a standard method of treatment for any condition other than BPH.

Background/Overview

Description of Condition

BPH is a disorder caused by the overgrowth of the prostate gland, which then interferes with the function of the bladder and urethra. BPH is sometimes referred to as benign prostatic hypertrophy. This condition usually results in the increased frequency of urination, frequent nighttime urination (nocturia), urinary hesitancy and urgency, and weak urinary stream. These symptoms appear slowly and progress gradually over years. BPH is relatively rare in younger men, affecting about 8% of men age 31 to 40 years. The incidence of BPH increases with age occurring in approximately 40% to 50% of men ages 51 to 60 years and over 80% of men older than age 80 years. Unless a man with BPH demonstrates symptoms that interfere with his quality of life and cannot be controlled with medical therapy, surgical intervention is rarely indicated.

Outcome Measures to Evaluate BPH Symptoms

A number of health status measures are used to evaluate symptoms relevant to BPH and adverse effects of treatment for BPH, including urinary dysfunction, severity of LUTS, ejaculatory dysfunction, overall sexual health, and overall quality of life. These measures include the AUASI, Benign Prostatic Hyperplasia Impact Index (BPH-II), IPSS, MSHQ-EjD, and the SHIM questionnaire. Please see the Definitions section for a description of each measurement scale or questionnaire as it evaluates symptoms related to BPH.

Description of Technology

Treatment alternatives for individuals with moderate to severe symptoms of BPH may include watchful waiting, medical therapies, complementary and alternative medicines (CAM), minimally invasive therapies, and surgical therapies (AUA, 2010). The oldest form of surgical treatment includes open prostatectomy, either approaching the surgical site through the abdomen or through the perineum. However, this approach has been associated with significant morbidity and long hospital stays and is currently reserved for treating prostates greater than 100 grams. TURP has been the preferred treatment modality for men with BPH for many years and it remains the standard against which other treatments are compared. During this procedure, surgical equipment is inserted into the urethra and guided to the area where the prostate constricts the urethral canal. Using a cutting tool, prostate tissue is excised leaving a cleared canal and a less massive prostate. The high rate of serious complications associated with TURP, along with the high prevalence of BPH, has encouraged development of alternative surgical treatments.

Other transurethral surgical and minimally invasive treatments for BPH are designed as an alternative to long-term medical therapy with the potential benefits of shorter hospital length of stay and decreased recovery time when compared to TURP. These surgical approaches include laser-based procedures, TUIP, TUVP, and minimally invasive procedures including TUMT, TUNA, and WIT. In these procedures, prostate tissue is removed through a

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heating method that destroys the desired amount of tissue that is reabsorbed by the body or expelled during urination. Following these procedures, as with TURP, a temporary catheter (tube) is left in the urethra to keep the urinary canal open while the surgical site heals. The catheter is then removed during a follow-up visit a few days after the surgery.

Definitions

Ablation: To surgically remove or excise a body part.

American Urological Association /Symptom Index (AUASI): A self-administered, 7-item questionnaire with a final score range of "0" (no symptoms) to "35" (worst symptoms), used to report the severity of lower urinary tract symptoms.

Benign prostate hyperplasia (BPH): A condition that causes an increase in the size of the prostate gland in men, commonly causing difficulty in urination; also referred to as benign prostatic hypertrophy.

Benign Prostatic Hyperplasia Impact Index (BPH-II): A self-administered, 4-item questionnaire with a final score range of "0" (best) to "13" (worst), used to measure the effect of urinary symptoms on health domains.

Contact laser ablation of the prostate (CLAP): A procedure where the tip of an Nd:YAG laser is placed in direct contact with prostate tissue, vaporizing it.

Cryosurgical: A treatment performed with an instrument that freezes and destroys abnormal tissue.

Holmium laser procedures of the prostate (HoLAP, HoLEP, HoLRP): Procedures that use a holmium laser fiber and specially adapted resectoscope to either ablate (HoLAP), enucleate (HoLEP), or resect (HoLRP) prostate tissue.

Hyperplasia: Enlargement of an organ or tissue because of an increase in the number of cells in that organ or tissue.

Hypertrophy: Enlargement or overgrowth of an organ or tissue due to an increase in size of its cells, rather than the number.

International Prostate Symptom Score (IPSS): An eight question, self-administered tool (seven symptom questions plus one quality of life question) used to screen for BPH-related symptoms.

Laser prostatectomy: A procedure that uses laser-generated heat to remove prostate tissue obstructing the urethra.

Lower urinary tract symptoms (LUTS): The chief complaint associated with BPH, typified by urinary frequency, urgency, nocturia, decreased and intermittent force of stream and the sensation of incomplete bladder emptying.

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Male Sexual Health Questionnaire for Ejaculatory Dysfunction (MSHQ-EjD): A self-administered questionnaire consisting of a 4-item scale measuring ejaculatory function.

Prostatic urethral lift (PUL): A permanently implanted lift device intended to hold the lateral prostatic lobes apart and create a passage through an obstructed prostatic urethra to improve the voiding channel.

Sexual Health Inventory for Men (SHIM): A self-administered, 5-item questionnaire consisting of a final score range of "1" (worst symptoms) to "25" (fewest symptoms) measuring erectile function.

Stent: A tube made of metal or plastic that is inserted into a vessel or passage to keep the lumen open and prevent closure due to a stricture or external compression.

Transurethral: A surgical approach to prostate surgery that involves the insertion of surgical tools through the urethra instead of through an incision in the skin.

Transuretheral incision of the prostate (TUIP): A surgical procedure involving one or more lengthwise incisions in the prostate near the bladder, which opens the bladder neck and prostate to reduce pressure on the urethra; usually limited to treating smaller prostate glands (equal to or less than 30 grams).

Transurethral microwave thermotherapy (TUMT): A minimally invasive treatment that uses microwave energy to heat and shrink the prostate to provide relief of urinary obstruction due to BPH.

Transurethral radiofrequency needle ablation (TUNA, RFNA): A non-surgical procedure in which low-level radiofrequency energy is delivered through a needle to a small area of the prostate, with the goal of relieving symptoms associated with BPH.

Transurethral vaporization of the prostate (TUVP): A surgical procedure where prostate tissue is vaporized using a grooved or spiked rollerball or thicker band-loop electrode, considered a modification of a transurethral resection of the prostate (TURP); also referred to as transurethral electrovaporization of the prostate (TUEVP, TUVAP, TUEVAP), transurethral evaporation (TUEP), or transurethral vapor resection of the prostate (TUVRP).

Vaporization procedures of the prostate: Procedures that use electrical energy to vaporize prostate tissues, differing from TURP and each other according to the type of electrode used and the magnitude of electrical energy applied. Prostate tissue is vaporized, resected into pieces or "chips," or coagulated.

Visually guided laser ablation of the prostate (VLAP): A non-contact laser ablation procedure where a Nd:YAG laser is held a short distance (two millimeters) from the prostate tissue, destroying it by coagulation and allowing it to slough away over several weeks; reserved for treating small or moderately small prostates (less than 80 grams).

Water-induced thermotherapy (WIT): A minimally invasive approach to the treatment of BPH involving the use of very hot water to shrink prostate tissue; also referred to as thermourethral hot water therapy.

Coding

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When services are Medically Necessary:

CPT

52450	Transurethral incision of prostate [TUIP]

ICD-10 Diagnosis

	All diagnoses

When services are also Medically Necessary:

CPT

52647	Laser coagulation of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included if performed)
52648	Laser vaporization of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, internal urethrotomy and transurethral resection of prostate are included if performed)
52649	Laser enucleation of the prostate with morcellation, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, internal urethrotomy and transurethral resection of prostate are included if performed) [HoLRP]
53850	Transurethral destruction of prostate tissue; by microwave thermotherapy [TUMT]
53852	Transurethral destruction of prostate tissue; by radiofrequency thermotherapy [when specified as RF needle ablation, RF TUNA, RFNA]
53899	Unlisted procedure, urinary system [when specified as transurethral destruction of prostate tissue: by water-induced thermotherapy (WIT)]

ICD-10 Procedure

0V507ZZ	Destruction of prostate, via natural or artificial opening
0V508ZZ	Destruction of prostate, via natural or artificial opening endoscopic

ICD-10 Diagnosis

N13.8	Other obstructive and reflux uropathy
N32.0	Bladder neck obstruction
N40.0-N40.3	Benign prostatic hyperplasia
R33.8	Other retention of urine
R33.9	Retention of urine, unspecified
R39.11-R39.198	Other difficulties with micturition

When services are Investigational and Not Medically Necessary:

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For the procedure codes listed above, for all other diagnoses or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

When services may be Medically Necessary when criteria are met:

CPT	
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
HCPCS	
C9739	Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants
C9740	Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants
ICD-10 Diagnosis	
N40.0-N40.3	Benign prostatic hyperplasia

When services are Investigational and Not Medically Necessary:
For the procedure codes listed above when criteria are not met or for all other diagnoses, or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

When services are Not Medically Necessary:
When the code describes a procedure indicated in the Position Statement section as not medically necessary.

CPT	
53899	Unlisted procedure, urinary system [when specified as transurethral balloon dilation of the prostatic urethra]
ICD-10 Diagnosis	
	All diagnoses

When services are Investigational and Not Medically Necessary:

CPT	
53854	Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy
53855	Insertion of a temporary prostatic urethral stent, including urethral measurement
ICD-10 Diagnosis	
	All diagnoses

When Services are also Investigational and Not Medically Necessary:

CPT

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37243	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction [when specified as prostatic arterial embolization]
55873	Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring)

ICD-10 Diagnosis

N13.8	Other obstructive and reflux uropathy
N32.0	Bladder neck obstruction
N40.0-N40.3	Benign prostatic hyperplasia
R33.8	Other retention of urine
R33.9	Retention of urine, unspecified
R39.11-R39.198	Other difficulties with micturition

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Websites for Additional Information

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GreenLight HPS® Laser System
GreenLight XPS™ Laser System
Holmium Laser (Ho:YAG)
Indigo LaserOptic Treatment® System
Neodymium-doped Yttrium Aluminum Garnet (Nd:YAG) Laser
Proleive Thermodilatation System
ProstaLund CoreTherm System
Prostatron System
Prostiva RF Therapy
Rezum System
Targis System

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The Spanner Temporary Prostatic Stent
TherMatrx Office Thermo Therapy
UroLift System

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Revised	06/06/2019	Medical Policy & Technology Assessment Committee (MPTAC) review. Prostatic urethral lift added to medically necessary statement with criteria for treatment of benign prostatic hyperplasia and changed to 'when criteria are not met' in investigational and not medically necessary statement. Prostatic urethral lift added to investigational and not medically necessary statement for treatment of genitourinary conditions other than benign prostatic hyperplasia. Updated Rationale, Coding, References, and Websites for Additional Information sections. Updated Coding section to remove C9748 deleted 12/31/2018.
	12/27/2018	Updated Coding section with 01/01/2019 CPT changes; added 53854.
Reviewed	07/26/2018	MPTAC review. Updated Rationale with AUA guideline recommendations for minimally invasive surgical techniques for management of LUTS attributed to BPH, References, and Websites for Additional Information sections.
Revised	11/02/2017	MPTAC review. The document header wording updated from "Current Effective Date" to "Publish Date." Administrative updates to the MN, NMN, and INV and NMN statements (removed abbreviations). Updated Description, Rationale, References, and Websites for Additional Information sections. Updated Coding section with 01/01/2018 HCPCS changes.
Reviewed	05/04/2017	MPTAC review. Updated Rationale, References, and Websites for Additional Information sections.
Revised	11/03/2016	MPTAC review. Clarification to the NMN statement. Revised INV and NMN statement for BPH, removing high-intensity focused ultrasound (HIFU) ablation from the document, with procedure being added to rescoped document, MED.00057. Updated Description, Rationale, Background, Definitions, Coding, References, and Websites for Additional Information sections.
Revised	08/04/2016	MPTAC review. Updated formatting in Position Statement section. Updated the Position Statement for treatments considered INV and NMN for BPH, adding transurethral convective water vapor thermal ablation (Rezum System). Updated Description, Rationale, Background, References, Websites for Additional Information, and Index sections. Updated Coding section to include ICD-10-CM changes effective 10/01/2016 and removal of ICD-9 codes.
Reviewed	08/06/2015	MPTAC review. Updated Rationale, Definitions, References, and Websites for Additional Information sections.
Reviewed	11/13/2014	MPTAC review. Updated Description, Rationale, References, and Websites for Additional Information sections. Other format changes throughout document. Updated Coding section with 01/01/2015 CPT changes.

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Revised	02/13/2014	MPTAC review. Combined existing investigational and not medically necessary statements for cryosurgical ablation and HIFU, adding new criteria for prostatic artery embolization (PAE) and prostatic urethral lift (PUL) for the treatment of symptomatic BPH. Updated and reordered Rationale section. Updated Background, Definitions, References, Websites for Additional Information, and Index sections. Updated Coding section to include 04/01/2014 HCPCS changes.
Reviewed	02/14/2013	MPTAC review. Updated Rationale, Coding, References, Websites for Additional Information, and Index.
Reviewed	02/16/2012	MPTAC review. Updated Rationale, Discussion, Coding, References, Websites for Additional Information, and Index.
Reviewed	05/19/2011	MPTAC review. Updated Rationale, Background, Definitions, References, and Index. Added section: Websites for Additional Information.
Reviewed	05/13/2010	MPTAC review. Updated Rationale, Coding, and References.
	01/01/2010	Updated Coding section with 01/01/2010 CPT changes; removed CPT 0084T deleted 12/31/2009.
Reviewed	05/21/2009	MPTAC review. Clarified medically necessary Position Statement, adding HoLAP and HoLEP as Holmium laser procedures; clarified VLAP statement, adding non-contact laser ablation of the prostate; added transurethral to electrovaporization and (TURVP, TUVP, TVP) acronyms. Clarified investigational and not medically necessary statement, adding (HoLAP, HoLEP) as Holmium laser procedures and non-contact laser ablation of the prostate to the VLAP statement. Updated Rationale, Discussion, Definitions, Index, and References.
	01/01/2009	Updated Coding section with 01/01/2009 CPT changes; removed CPT 53853 deleted 12/31/2008.
Revised	05/14/2008	MPTAC review. Revised document title to address the surgical and minimally invasive treatments that are considered investigational and not medically necessary for all genitourinary conditions other than BPH. Updated Rationale and References.
Revised	02/21/2008	MPTAC review. Revised document title from Surgery for Benign Prostatic Hypertrophy (BPH) to Surgical and Minimally Invasive Treatments for Benign Prostatic Hyperplasia (BPH). Reformatted and separated Position Statements to identify surgical and minimally invasive procedures. Updated Rationale, Background, Definitions, and References.
	01/01/2008	Updated Coding section with 01/01/2008 CPT changes; removed CPT 52510 deleted 12/31/2007. The phrase "investigational/not medically necessary" was clarified to read "investigational and not medically necessary." This change was approved at the November 29, 2007 MPTAC meeting.
Revised	03/08/2007	MPTAC review. Position Statement change, medically necessary criteria revised. Rationale and References updated.
Reviewed	03/23/2006	MPTAC review. Updated References.
	01/01/2006	Updated Coding section with 01/01/2006 CPT/HCPCS changes.
	11/18/2005	Added reference for Centers for Medicare and Medicaid Services (CMS) – National Coverage Determination (NCD).

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

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Historical

Revised	04/28/2005	MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization.

Pre-Merger Organizations	Last Review Date	Document Number	Title
Anthem, Inc.	01/13/2005	SURG.00028	Surgery for Benign Prostatic Hypertrophy (BPH)
WellPoint Health Networks, Inc.	12/02/2004	3.08.02	Treatment of Benign Prostatic Hypertrophy
	12/02/2004	3.08.05	Temporary Prostatic Stent

Historical

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