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 (BPH), 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 (TURP).

Note: Please see the following related documents for additional information:

- SURG.00025 Cryosurgical Ablation of Solid Tumors Outside the Liver
- SURG.00094 High Intensity Focused Ultrasound (HIFU) for the Treatment of Prostate Cancer

Position Statement

Medically Necessary:

The following surgical procedures are considered medically necessary as an alternative to open prostatectomy or transurethral resection of the prostate (TURP) for the treatment of benign prostatic hyperplasia (BPH):

1. Laser-based procedures that have received U.S. Food and Drug Administration (FDA) approval include, but are not limited to, any of the following:
   - Contact laser ablation of the prostate (CLAP); or
   - Holmium laser procedures, including Holmium laser ablation of the prostate (HoLAP), Holmium laser enucleation of the prostate (HoLEP), and Holmium laser resection of the prostate (HoLRP); or
   - Interstitial laser coagulation of the prostate (ILCP); or
   - Photoselective laser vaporization of the prostate (PVP); or
   - Transurethral ultrasound guided laser induced prostatectomy (TULIP); or
   - Visually guided laser ablation of the prostate (VLAP), also called non-contact laser ablation of the prostate; OR

2. Transurethral incision of the prostate (TUIP); OR
3. Transurethral radiofrequency needle ablation (RFNA), also called transurethral needle ablation (TUNA); OR
4. Transurethral vapor resection of the prostate (TUVRP), also called transurethral electrovaporization of the prostate (TUEVP, TUVAP, or TUEVAP), transurethral evaporation (TUEP), or transurethral vaporization of the prostate (TUVP, TVP).

The following minimally invasive procedures are considered medically necessary as an alternative to open prostatectomy or TURP for the treatment of BPH:

1. Water-induced thermotherapy (WIT), also called thermourethral hot-water therapy; or
2. Transurethral microwave thermotherapy (TUMT).

Not Medically Necessary:

Endoscopic balloon dilation of the prostatic urethra for the treatment for BPH is considered not medically necessary.
Investigational and Not Medically Necessary:

The following procedures are considered *investigational and not medically necessary* for the treatment of BPH:

1. Cryosurgical ablation; or
2. High-intensity focused ultrasound (HIFU) ablation; or
3. Prostatic arterial embolization; or
4. Prostatic urethral lift.

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

The following procedures are considered *investigational and not medically necessary* for all genitourinary conditions other than BPH:

1. Contact laser ablation of the prostate (CLAP); or
2. Holmium laser procedures of the prostate (HoLAP, HoLEP, HoLRP); or
3. Interstitial laser coagulation of the prostate (ILCP); or
4. Photoselective laser vaporization of the prostate (PVP); or
5. Transurethral microwave thermotherapy (TUMT); or
6. Transurethral radiofrequency needle ablation (RFNA), also called transurethral needle ablation (TUNA); or
7. Transurethral ultrasound guided laser induced prostatectomy (TULIP); or
8. Visually guided laser ablation of the prostate (VLAP), also called non-contact laser ablation of the prostate; or
9. Water-induced thermotherapy (WIT), also called thermourethral hot-water therapy.

**Rationale**

**Surgical and Minimally Invasive Treatments for BPH**

Standard surgical treatments for BPH are some of the most common therapies in medical practice but as a management option are typically performed in the operating room setting, require anesthesia, and may be associated with a greater risk for morbidity. Surgical treatments such as open prostatectomy and 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 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.

According to the American Urological Association (AUA, 2010):

Traditionally, the gold standards have been an open prostatectomy (retropubic, suprapubic) for very large prostates or those with large bladder calculi and a monopolar transurethral resection of the prostate (TURP). For small prostates (less than 30 gm), the option for a transurethral incision of the prostate (TUIP) has been found to be associated with fewer complications but comparable efficacy.

Laser-based prostatectomy procedures including potassium-titanyl-phosphate photovaporization (Al-Ansari, 2010; Araki, 2008; Elmansy, 2010; Elshal, 2015; Rusvat, 2008, Stafinski, 2008, Tugcu, 2008) and other surgical and minimally invasive treatments including TUIP (Riehmann, 1995; Tkocz, 2002), TUMT, RFNA/TUNA (Bouza, 2006; Boyle, 2004; Hill, 2004; Hindley, 2001; Roehrborn, 1999), and 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 HoLAP (Elmansy, 2010), HoLEP (Ahyai, 2007; Elzayat, 2007; Kuntz, 2008; Shah, 2007; Tan, 2007; Wilson, 2006) and 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 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; Prolique 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 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 Artery 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. Early results from a United States clinical trial evaluate the efficacy and safety of PAE in 20 men with BPH (Bagla, 2014). Following embolization, 19 of 20 participants experienced average AUA symptom score improvements of 10.8 points (p<0.0001), 12.1 points (p=0.0003) and 9.8 points (p=0.007) at 1, 3, and 6 months, respectively. Improvements were also reported in quality of life-related symptoms and sexual function. Prostate volume decreased 18% (p=0.05) in 5 individuals at 6 months. Limitations of this trial include lack of a comparator treatment group, blinding, and randomization, the small sample size, and short-term follow-up of outcome measures.

Pisco and colleagues (2013) conducted two prospective, nonrandomized studies in Portugal evaluating short-, intermediate-, and mid-term outcomes of PAE in men with BPH. The largest study with mid-term results evaluated 255 participants for a mean follow-up period of 10 months (range 1-36 months). All participants were on medical therapy for BPH with persistent moderate to severe symptoms for more than 6 months. Eight participants had TURP years before and 32 participants had bladder catheters at the time due to acute urinary retention. PAE was reported as "technically successful" in 238 of 250 participants, defined as PAE completed in at least 1 pelvic side. Clinical success was reported as the mean value over time of response to effectiveness variables including International Prostate Symptom Score (IPSS), quality of life score, International Index Erectile Function (IIEF), uroflowmetry, and prostate specific antigen (PSA) levels and volume. Most clinical changes and success occurred in the first month after PAE in 195 (81.9%) participants with clinical failures in 43 (18.1%) participants. Cumulative rates of clinical success, defined as improving symptoms and quality of life, at 6 and 12 months were 78% and 75%, respectively. A statistically significant improvement over time of all evaluated parameters was observed; however, there was not a relationship between the reduction in prostatic volume and the clinical outcome (p=0.12). An improvement in the mean uroflowmetry obtained after PAE was modest compared to individuals who are treated surgically by TURP, reported as 51% for PAE compared to 125% for TURP. Additional study with long-term follow-up is needed to address the question of longevity of this PAE outcome. There was only one major complication reported (bladder ischemia) and no cases of sexual dysfunction including impotence or retrograde ejaculation. Limitations of this single-center study include lack of randomization, absence of a comparator treatment group, and short-term follow-up of outcome measurements; a potential bias also exists concerning the use of questionnaires to validate subjective outcome measures.

PAE for symptomatic BPH has been assessed in small case series and single-center studies evaluating measures of clinical symptom improvement (Carneval, 2013; Rio Tinto, 2012), 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. Despite some promising preliminary results, including the potential for reduced morbidity and avoidance of general anesthesia, additional multicenter randomized controlled trials with long-term follow-up are needed to evaluate the safety and durability of the clinical benefits of PAE over standard surgical procedures for the treatment of moderate to severe lower urinary tract symptoms (LUTS) secondary to BPH.

A National Institute for Health and Care Excellence (NICE, 2013) interventional procedure guidance for PAE for BPH states:

Current evidence on the safety and efficacy of prostate artery embolization for benign prostatic hyperplasia is inadequate in quantity and quality. Therefore, this procedure should only be used in the context of research. Further research in the form of randomized trials or cohort studies (for example, using an appropriate register) should clearly document patient selection criteria and all complications, specifically including disturbance of sexual function. Efficacy outcomes should include measure of urinary function, symptoms and quality of life. Information about longer-term outcomes, including the need for further treatment, would be valuable.

The current AUA Guideline on the Management of Benign Prostatic Hyperplasia (BPH) (2010) does not address the use of PAE for the treatment of BPH.

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.

Prostatic Urethral Lift (PUL) System

The PUL system is a minimally invasive treatment for symptomatic LUTS secondary to BPH. 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 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.

Chin and colleagues (2012) evaluated the 2-year results of the UroLift in an industry-sponsored, prospective, nonrandomized multicenter Australia-based trial of 64 men, ages 55 years or older, with moderate to severe symptomatic BPH. The implant technique was refined during the course of the study using cystoscopic and symptomatic results from participants treated early in the study. To evaluate effectiveness, a general estimating equation model was adapted to each output parameter, including IPSS, quality of life, BPH Impact Index (BPHII), and peak urethral flow rate assessed at 2 weeks, and 3, 6, 12, and 24 months. In the evaluable participants, IPSS was reduced from the baseline by 42%, 49%, and 42% at 2 weeks, 6 months, and 2 years, respectively. No compromise in sexual function was observed after treatment and the average Sexual Health Inventory for Men (SHIM) questionnaire score at each follow-up interval was slightly increased compared with baseline, although these differences were not statistically significant. The early postoperative course was typical of an endoscopic procedure in terms of irritative symptoms, including dysuria and mild hematuria, which resolved in the first week. Other post-procedure adverse events included epididymo-orchitis (n=1), rigor (n=1), prostatitis (n=1), and urinary tract infection (n=7). A total of 34 of 64 participants (53%) required postoperative catheterization; however, 75% of the catheters were removed the day after the implant procedure. Two participants underwent TURP within 30 days due to lack of response to the PUL. No compromise in erectile or ejaculatory function was observed. At the end of 2-year follow-up, 20% (13 of 64) of participants underwent TURP, PVP, or repeat PUL procedures due to return of LUTS. Limitations of this study include lack of an active or sham control group, limited sample size for some
outcome measures, lack of inclusion criteria related to sexual function or sexual activity, limited durability of results for some participants as the device was changed and implant procedural technique refined during the course of the study, and lack of sustained response and return of LUTS in 20% of participants after PUL implant (which required repeat treatment).

Roehrborn and colleagues (2013) reported result of the multicenter prospective trial (L.I.F.T.) of the UroLift System for the treatment of LUTS secondary to BPH. 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, 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, ages 50 years or older, with AUA Symptom Index (AUASI) 13 or greater, maximum flow rate 12 milliliters per second or less, and a prostate size of 30 to 89 cubic centimeters 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 peak flow rate (Qmax) at 3 and 12 months, IPSS at 2 weeks, and quality of life and BPHII at 12 months. The primary safety endpoint was to demonstrate an observed rate of \( \leq 10\% \) postoperative urinary catheterization for more than 7 days. After the 3-month endpoint, all participants were unblinded to treatment; 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 study. 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). Peak urinary flow rate (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 IIEF. Two serious adverse events were 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 an industry-sponsored crossover study recruiting participants who received sham treatment during the L.I.F.T. trial (Roehrborn, 2013). 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.

Additional case series have evaluated data obtained from the 2-year nonrandomized trial (Chin, 2012) and the L.I.F.T. trial (Roehrborn, 2013) for treatment of LUTS secondary to BPH. These retrospective reviews evaluate preservation of sexual function (McVary, 2014; Woo, 2012) and improvement in voiding flow, symptom relief, and the surgical technique involved with minimally invasive PUL in men with a history of symptomatic BPH (McNicholas, 2013). In the McNicholas study (2013), 102 participants were successfully implanted with a mean of 4.5 implants with no reported serious adverse events. The mean IPSS, quality of life, and peak flow rate score improved 36%, 39%, and 38% by 2 weeks, and 52%, 53%, and 51% at 2 months (p<0.001), respectively. The analysis did not collect sexual function data using a validated data collection tool. A total of 4 (6.5%) participants experienced insufficient improvement and TURP was performed without complications. Limitations of this study include analysis of participant records from a nonblinded single-arm registry, lack of comparator treatments, and short-term follow-up intervals. Shore and colleagues (2014) performed an open-label study of 51 participants treated with PUL for BPH, attempting to further characterize the "perioperative subject experience" with the procedure, in terms of
Perera and colleagues (2014) performed a systematic review and meta-analysis of the retrospective and prospective studies evaluating symptomatic, functional, and sexual outcomes following the PUL procedure. A total of 10 publications (including the studies previously addressed in the Rationale of this document) were included in the analysis pooling estimates from 452 and 680 treated individuals. At 12-months follow-up, an improvement of LUTS symptoms was observed when estimated on the IPSS scale (improvement of -0.8 points, 95% confidence interval [CI], -8.8 to 7.2). Assessment of functional outcomes (Qmax, post-void residual [PVR]) was limited due to inconsistent reporting at selected intervals in some of the studies. Pooled estimates were observed for Qmax with an improvement of between 3.80 ml/s (95% CI, 3.0-4.6) and 4.0 ml/s (95% CI, 3.4-4.6) during 1 month and 12 months in 3 studies; however, the authors suggested "the values obtained are not suitable for direct comparisons with alternative therapies, and the resulting improvements in Qmax should be considered with caution." Despite the functional improvements in Qmax which appear noninferior in this meta-analysis, when compared with current medical and minimally invasive therapies, these "...improvements following PUL are fewer than those following surgical interventions including TURP and PVP, which are associated with an improved Qmax of between 10 and 13 ml/s at 12 months follow-up." Sexual function was reported as preserved with a consistently small improvement estimated throughout follow-up (standardized mean gain range, 0.3-0.4). Limitations of this analysis include a high degree of heterogeneity and varying quality in the reviewed studies. The long-term durability of the device could not be commented on with only a 12-month follow-up. Publication bias and favorable reporting could not be discounted "owing to commercial interests with the current method of PUL." The authors concluded that longer follow-up and larger randomized comparative studies are needed as the "current evidence suggests that the currently described PUL procedure requires alteration to improve functional performance for equivalence with surgical interventions."

Sønksen and colleagues (2015) reported on the 12-month results of the BPH6 study, a prospective, randomized study conducted across 3 European countries (10 centers) comparing PUL (n=45) to TURP (n=35) in 80 participants 50 years of age and older who were candidates for TURP. After initial 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 6 elements (that is, symptom relief, quality of recovery, erectile function preservation, ejaculatory function preservation, continence preservation, and safety) with the overall objective "to show that the success rate for PUL is not inferior to TURP in terms of the composite endpoint at 12 mo." Noninferiority was evaluated using a 1-sided lower 95% CI for the difference between PUL and TURP performance. Participants were matched between the study arms, with no statistically significant differences in baseline parameters except for Male Sexual Health Questionnaire for Ejaculatory Dysfunction (MSHQ-EJD) score; only 1 participant was excluded from the final analysis for a study protocol violation. In addition to PUL participants consistently demonstrating a more rapid recovery than TURP participants, significant improvements were observed in both study groups over time in IPSS, IPSS quality of life, BPH impact index, and Qmax; however, IPSS, Qmax, and PVR were better after TURP than after PUL (p<0.05). Erectile function was preserved in both PUL and TURP groups with only 1 participant in the PUL group (2.6%) and 2 participants in the TURP group (6.1%) experiencing a consistent drop in SHIM score after the procedure. The proportion of participants who met the original BPH6 primary endpoint was 34.9% for the PUL group and 8.6% for the TURP group (noninferiority, p=0.0002; superiority, p=0.006). After adjusting for any difference 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). Reintervention for treatment failure occurred in 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 (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.

The long-term safety, efficacy, and durability of PUL for moderate to severe BPH are reported in the 3-year results of the L.I.F.T study (Roehrborn, 2015). After randomized comparison at 3 months, 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 participants (66.4%) (those subjects allocated to PUL and included in the ITT analysis performed at 3 months) were included in the final 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 study 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. Additional randomized studies with ITT analysis of longitudinal data are needed to compare the clinical efficacy and durability of PUL to other minimally invasive and surgical interventions for the treatment of LUTS from BPH.

The current AUA's Guideline on the Management of BPH (2010) does not address the use of PUL for the treatment of BPH. An interventional procedure guidance for PUL for BPH published by NICE (2014) includes the following recommendations:

Current evidence on the efficacy and safety of insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent, and audit. During the consent process clinicians should, in particular, advise patients about the range of possible treatment options and the possible need for further procedures if symptoms recur...NICE encourages further research and publication of results from consecutive case series of patients having this procedure.

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. Intraprostatic 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.

In The Spanner clinical investigation (Dineen, 2008; Shore, 2007), a total of 186 male subjects, 45 years of age and older, 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 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 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.

Grimsley and colleagues (2007) retrospectively reviewed a series of 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 5 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. Additional study is needed to establish if use of The Spanner stent results in clinically significant improvement in health outcomes.

In summary, larger randomized controlled trials comparing minimally invasive treatments, including PAE, PUL, and temporary prostatic stents, are needed to determine their long-term efficacy compared to standard treatments for BPH.

Other Treatments for BPH

The AUA's updated Guideline on the Management of Benign Prostatic Hyperplasia (BPH) 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, HIFU 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
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).

HIFU ablation is a minimally invasive procedure using a transrectal ultrasound probe to image the prostate and deliver timed bursts of heat to create coagulation necrosis in a targeted area without harming adjacent healthy tissue (Leslie, 2006). Schatzl and colleagues (2000) compared the efficacy of TURP to 4 less invasive treatment options including HIFU in a small clinical trial. Randomization was attempted but could not be carried out because participant characteristics such as prostate size, prostatic calcifications and middle lobes limited the types of individuals who could receive the different treatments. The individuals who received HIFU tended to have smaller prostates and less severe symptoms than those who received TURP. A second study reported by Madersbacher and colleagues (2000) attempted to determine the long-term outcome after HIFU therapy for individuals with LUTS due to BPH. The data collected between June 1992 and March 1995 indicated that HIFU therapy for BPH, at least in its present form, did not "stand the test of time," as 43.8% of individuals had to undergo TURP within 4 years after initial therapy. Additional long-term studies are warranted to reliably assess the role of HIFU as an established alternative to standard treatments for BPH.

**Surgical and Minimally Invasive Treatments for Genitourinary Conditions Other Than BPH**

The efficacy of surgical and minimally invasive procedures including CLAP, holmium laser procedures, ILCP, PVP, RFNA/TUNA, TULIP, TUMT, VLAP, and WIT has not been established as treatment for prostatic or other genitourinary conditions other than BPH. The AUA's *Guideline for the Management of Clinically Localized Prostate Cancer* (AUA, 2010), the National Cancer Institute's Prostate Cancer Treatment (PDQ®) (NCI, 2015), and the National Comprehensive Cancer Network® (NCCN) Clinical Practice Guidelines in Oncology-Prostate Cancer (V1.2015) do not address 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.

#### 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 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.

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.

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.

High-intensity focused ultrasound (HIFU) ablation of the prostate: A procedure that uses timed bursts of ultrasound to create coagulation necrosis in a targeted area of the prostate.

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.

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.

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.

Transurethral incision of the prostate (TUIP): A surgical procedure involving one or more lengthwise
In 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 evacution 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**

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Medically Necessary:

<table>
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<tr>
<th>CPT</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>52450</td>
<td>Transurethral incision of prostate [TUIP]</td>
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**ICD-10 Diagnosis**

*For dates of service on or after 10/01/2015*

All diagnoses

**ICD-9 Diagnosis**

*For dates of service prior to 10/01/2015*

All diagnoses

When services are also Medically Necessary:

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<td>52647</td>
<td>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)</td>
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<td>52648</td>
<td>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)</td>
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<td>52649</td>
<td>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]</td>
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<td>Code</td>
<td>Description and Code Details</td>
</tr>
<tr>
<td>--------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
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<tr>
<td>53850</td>
<td>Transurethral destruction of prostate tissue; by microwave thermotherapy [TUMT]</td>
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<tr>
<td>53852</td>
<td>Transurethral destruction of prostate tissue; by radiofrequency thermotherapy [needle ablation, TUNA, RFNA]</td>
</tr>
<tr>
<td>53899</td>
<td>Unlisted procedure, urinary system [when specified as transurethral destruction of prostate tissue: by water-induced thermotherapy (WIT)]</td>
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</table>

**ICD-10 Procedure**  
*For dates of service on or after 10/01/2015*

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

**ICD-10 Diagnosis**  
*For dates of service on or after 10/01/2015*

- N13.8  
  Other obstructive and reflux uropathy
- N32.0  
  Bladder neck obstruction
- N40.0-N40.3  
  Enlarged prostate
- R33.8  
  Other retention of urine
- R33.9  
  Retention of urine, unspecified
- R39.11-R39.19  
  Other difficulties with micturition

**ICD-9 Procedure**  
*For dates of service prior to 10/01/2015*

- 60.21  
  Transurethral (ultrasound) guided laser induced prostatectomy (TULIP)
- 60.96  
  Transurethreal destruction of prostate tissue by microwave thermotherapy
- 60.97  
  Other transurethreal destruction of prostate tissue by other thermotherapy

**ICD-9 Diagnosis**  
*For dates of service prior to 10/01/2015*

- 596.0  
  Bladder neck obstruction
- 600.00-600.91  
  Hyperplasia of prostate
- 788.20-788.29  
  Retention of urine

**When services are Investigational and Not Medically Necessary:**

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 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**  
*For dates of service on or after 10/01/2015*

- All diagnoses

**ICD-9 Procedure**  
*For dates of service prior to 10/01/2015*

- 60.95  
  Transurethral balloon dilation of the prostatic urethra

**ICD-9 Diagnosis**  
*For dates of service prior to 10/01/2015*

- All diagnoses

**When services are Investigational and Not Medically Necessary:**

**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
- 53855  
  Insertion of a temporary prostatic urethral stent, including urethral measurement

**HCPCS**

- C9739  
  Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants
C9740 Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants

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<td>37243</td>
<td>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]</td>
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<tr>
<td>55873</td>
<td>Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring)</td>
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<tr>
<td>55899</td>
<td>Unlisted procedure, male genital system [when specified as destruction of prostate tissue by high intensity focused ultrasound]</td>
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<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>C9734</td>
<td>Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (MR) guidance</td>
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**ICD-10 Diagnosis**

*For dates of service on or after 10/01/2015*

- N13.8 Other obstructive and reflux uropathy
- N32.0 Bladder neck obstruction
- N40.0-N40.3 Enlarged prostate
- R33.8 Other retention of urine
- R33.9 Retention of urine, unspecified
- R39.11-R39.19 Other difficulties with micturition

**ICD-9 Diagnosis**

*For dates of service prior to 10/01/2015*

- 596.0 Bladder neck obstruction
- 600.00-600.91 Hyperplasia of prostate
- 788.20-788.29 Retention of urine

**References**


35. Norby B, Nielsen HV, Drimodt-Moller PC. Transurethral interstitial laser coagulation of the prostate and transurethral microwave thermotherapy vs. transurethral resection or incision of the prostate: results of a randomized, controlled study in patients with symptomatic BPH. BJU Int. 2002; 90(9):853-862.


**Government Agency, Medical Society, and Other Authoritative Publications:**


Websites for Additional Information


Index

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
Targis System
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

<table>
<thead>
<tr>
<th>Status</th>
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<tr>
<td>Reviewed</td>
<td>08/06/2015</td>
<td>Medical Policy &amp; Technology Assessment Committee (MPTAC) review. Updated Rationale, Definitions, References, and Websites for Additional Information sections.</td>
</tr>
<tr>
<td>Reviewed</td>
<td>11/13/2014</td>
<td>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.</td>
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<tr>
<td>Revised</td>
<td>02/13/2014</td>
<td>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.</td>
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<td>02/14/2013</td>
<td>MPTAC review. Updated Rationale, Coding, References, Websites for Additional Information, and Index.</td>
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<td>Reviewed</td>
<td>02/16/2012</td>
<td>MPTAC review. Updated Rationale, Discussion, Coding, References, Websites for Additional Information, and Index.</td>
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<tr>
<td>Reviewed</td>
<td>05/19/2011</td>
<td>MPTAC review. Updated Rationale, Background, Definitions, References, and Index. Added section: Websites for Additional Information.</td>
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<td>05/13/2010</td>
<td>MPTAC review. Updated Rationale, Coding, and References.</td>
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<td>01/01/2010</td>
<td>Updated Coding section with 01/01/2010 CPT changes; removed CPT</td>
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0084T deleted 12/31/2009.

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.

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.

02/21/2008 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.

03/08/2007 MPTAC review. Position Statement change, medically necessary criteria revised. Rationale and References updated.

03/23/2006 MPTAC review. Updated References.


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

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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