Medical Coverage Policy

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Benign Prostatic Hyperplasia (BPH) Surgical Treatments

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Related Coverage Resources

Botulinum Therapy
High Intensity Focused Ultrasound (HIFU)
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INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers

must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses surgical and minimally invasive procedures used in the treatment of benign prostatic hyperplasia (BPH).

Coverage Policy

The following treatments for benign prostatic hyperplasia (BPH) are considered not medically necessary:

- absolute ethanol injection
- high-intensity focused ultrasound (HIFU)
- histotripsy
- temporary implantable nitinol device (TIND)
- transrectal thermal therapy
- transurethral balloon dilation of the prostatic urethra
- water-induced thermotherapy (WIT)

Note: Pharmacologic therapy is not considered within the scope of this Medical Coverage Policy. Please refer to the applicable pharmacy benefit to determine availability and the terms and conditions of coverage related to the treatment of BPH.

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

Benign prostatic hyperplasia (BPH) is the most common prostate condition in men over 50, affecting approximately 14 million men in the U.S. as of 2010. Its prevalence increases with age, impacting about 50% of men aged 51–60 and up to 90% of those over 80 (National Institutes of Diabetes and Digestive and Kidney Diseases (NIDDK, 2014).

Racial and ethnic disparities in BPH diagnosis and treatment have been documented. A 2020 American Urological Association (AUA) press release highlighted that African American and Hispanic men may be under- or untreated for BPH in outpatient settings. A retrospective review of regional hospital network database information by Antoine et al. (2022) found that Black and

other non-white patients were significantly less likely than white patients to undergo surgical treatment for BPH, even after adjusting for age, insurance, comorbidities, and medication type. The authors suggested that implicit bias, patient attitudes, or structural barriers may contribute to this disparity, though the findings may not be generalizable nationwide. Similarly, Narang et al. (2023) analyzed Medicare claims data and found that Black, Indigenous, and People of Color (BIPOC) men had a 19% lower likelihood of receiving BPH surgery compared to white men. BIPOC patients were also more likely to undergo surgery in inpatient settings. Finally, a 2025 systematic review by Nguyen et al. revealed that none of the included 37 randomized controlled trials on minimally invasive surgical therapies (MISTs) for BPH reported participants' race or ethnicity. This omission limits the generalizability of findings and may perpetuate inequities, particularly for African American men who are more likely to experience severe disease and less likely to receive timely surgical care.

General Background

Benign prostatic hyperplasia (BPH) is a common condition caused by the abnormal growth of non-malignant prostate cells in men that can result in bothersome lower urinary tract symptoms (LUTS) (e.g., urinary urgency and frequency, weak stream and straining, urinary obstruction or retention, renal insufficiency, hydronephrosis, recurrent gross hematuria, recurrent or persistent urinary tract infections, urosepsis, large bladder diverticula, and bladder stones) (Franco, et al., 2021). The most frequent indications for surgical management are moderate-to-severe voiding symptoms that are refractory to medical management.

Treatment of BPH is individualized to the patient and involves evaluation of symptoms along with objective findings from examination and laboratory results. Initial treatment for BPH is usually drug therapy (e.g., alpha blocker, PDE5 Inhibitor, finasteride/dutasteride) designed to relieve obstruction, but this often provides only modest relief, and up to 30% of patients require surgical intervention. Long-term use of medications for LUTS/BPH has also been associated with cognitive issues and depression. There are several proposed surgical treatments for BPH that involve burning, cutting, or removal of prostatic tissue. (Moul, et al., 2019; Sandhu, et al., 2023). Transurethral resection of the prostate (TURP) is considered the gold standard for surgical treatment of BPH. However, several other minimally invasive surgical procedures and therapies have been widely used and are supported by relevant professional societies. Generally, data in the published, peer-reviewed literature demonstrate improved outcomes and support the safety and effectiveness of these other established therapies (NeoTract, 2023; Sandhu, et al., 2023; AMA, 2021; Elterman, et al., 2021; Bach, et al., 2020; Desai, et al., 2020; Hayes, 2020; Kasraeian, et al., 2020; Tanneru, et al., 2020; Hwang, et al., 2019; Hwant, et al., 2019; Jung, et al., 2019; Pimentel, et al., 2019; Gilling, et al., 2018, 2019, 2020; Hayes, 2018, annual review 2020; Kasivisvanathan, et al., 2018; McVary and Roehrborn, 2018; Darson, et al., 2017; Gratzke, et al., 2017; Bozkurt, et al., 2016; Jones, et al., 2016; Rukstalis, et al., 2016; Dixon, et al., 2015, 2016; Perera, et al., 2015; Sønksen, et al., 2015; Cantwell, et al., 2014; McVary, et al., 2014, 2016, 2021; Shore, et al., 2014; McNicholas, et al., 2013; Roehrborn, et al., 2013, 2016, 2017; Barkin, et al., 2012; Chin, et al., 2012; Woo, et al., 2011). These surgeries and therapies include:

- Contact laser ablation of the prostate (CLAP)
- Holmium laser ablation, enucleation, resection (HoLAP, HoLEP, HoLRP)
- Laser vaporization and laser ablation/coagulation)
- Open/laparoscopic prostatectomy
- Photoselective vaporization of the prostate (PVP)
- Prostatic Urethral lift (e.g., UroLift)
- Stents (e.g., UroLume® endourethral prosthesis)

- Transurethral electrovaporization (TUVP, TVP, TUEP), also known as transurethral vapor resection of the prostate (TUVRP)
- Transurethral incision of the prostate (TUIP)
- Transurethral microwave thermotherapy (TUMT)
- Transurethral needle ablation (TUNA), also known as radiofrequency needle ablation (RFNA)
- Transurethral resection of the prostate (TURP)
- Water vapor thermal therapy (e.g., Rezūm System)
- Waterjet tissue ablation (e.g., AquaBeam System)

Professional Societies/Organizations: In a 2023 updated guideline on the management of BPH/LUTS (Sandhu, et al., 2023), the American Urological Association stated that "surgery is recommended for patients who have renal insufficiency secondary to BPH, refractory urinary retention secondary to BPH, recurrent urinary tract infections (UTIs), recurrent bladder stones or gross hematuria due to BPH, and/or with LUTS/BPH refractory to or unwilling to use other therapies". This recommendation is based upon clinical principle (i.e., widely agreed upon by urologists or other clinicians). The following surgical therapies are recommended by the society:

- "TURP should be offered as a treatment option for patients with LUTS/BPH. (Moderate Recommendation; Evidence Level: Grade B)
    - Clinicians may use a monopolar or bipolar approach to TURP as a treatment option, depending on their expertise with these techniques. (Expert Opinion)
- Open, laparoscopic, or robotic assisted prostatectomy should be considered as treatment options by clinicians, depending on their expertise with these techniques, only in patients with large to very large prostates. (Moderate Recommendation; Evidence Level: Grade C)
- TUIP should be offered as an option for patients with prostates ≤30cc for the surgical treatment of LUTS/BPH. (Moderate Recommendation; Evidence Level: Grade B)
- Bipolar TUVP may be offered as an option to patients for the treatment of LUTS/BPH. (Conditional Recommendation; Evidence Level: Grade B)
- PVP should be offered as an option using 120W or 180W platforms for the treatment of LUTS/BPH. (Moderate Recommendation; Evidence Level: Grade B)
- PUL should be considered as a treatment option for patients with LUTS/BPH provided prostate volume 30-80cc and verified absence of an obstructive middle lobe. (Moderate Recommendation; Evidence Level: Grade C)
    - PUL may be offered as a treatment option to eligible patients who desire preservation of erectile and ejaculatory function. (Conditional Recommendation; Evidence Level: Grade C)
- TUMT may be offered as a treatment option to patients with LUTS/BPH. (Conditional Recommendation; Evidence Level: Grade C)
- WVTT should be considered as a treatment option for patients with LUTS/BPH provided prostate volume 30-80cc. (Moderate Recommendation; Evidence Level: Grade C)
    - WVTT may be offered as a treatment option to eligible patients who desire preservation of erectile and ejaculatory function. (Conditional Recommendation; Evidence Level: Grade C)
- Holmium laser enucleation of the prostate (HoLEP) or thulium laser enucleation of the prostate (ThuLEP) should be considered as an option, depending on the clinician's expertise with these techniques, as prostate size-independent options for the treatment of LUTS/BPH. (Moderate Recommendation; Evidence Level: Grade B)
- Robotic waterjet treatment (RWT) may be offered as a treatment option to patients with LUTS/BPH provided prostate volume 30-80cc. (Conditional Recommendation; Evidence Level: Grade C)
- HoLEP, PVP, and ThuLEP should be considered as treatment options in patients who are at higher risk of bleeding. (Expert Opinion)"

In the 2023 update to the guideline on the management of LUTS attributed to BPH (Sandhu, et al., 2023), the AUA removed the statements for TUMT and TUNA as these are now viewed by the AUA as "legacy technologies" that have been historically used but are being "displaced" with newer minimally invasive technologies. Additionally, an expert opinion recommendation was given for the use of temporary implanted prostatic devices (TIPD) (also known as temporary implantable nitinol device; TIND) as "a treatment option for patients with LUTS/BPH provided prostate volume is between 25 and 75cc and lack of obstructive median lobe." Expert opinion recommendations are given by the AUA when there is an absence of sufficient evidence to assign a strength rating of A (high), B (moderate), or C (low).

Professional Societies/Organizations:
The American Urological Association (AUA) evidence-based guideline, "Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia" addresses surgical and minimally invasive procedures used in the treatment of benign prostatic hyperplasia (BPH) (Sandhu, et al., 2023). The AUA states that clinical scenarios exist where conservative management (e.g., medications), used alone or in combination with a minimally invasive surgery, is either inadequate or inappropriate (e.g., renal insufficiency, patient preference) in which case consideration of one of the more invasive treatment modalities is warranted.

Additional Therapies:
Numerous other therapies have been proposed for the treatment of BPH however, to date there is insufficient evidence in the published peer-reviewed scientific literature to demonstrate safety and effectiveness of these therapies.

Absolute Ethanol Injection: Absolute Ethanol Injection is a minimally invasive procedure that can be performed in an outpatient setting and has been proposed as a treatment for benign prostatic hypertrophy (BPH). Ethanol injection is performed using dehydrated ethanol injected with a flexible injection needle through the side channel of a cystoscope and into the targeted tissue. The result is coagulation necrosis (chemoablation) aimed at destroying the enlarged tissue (Sakr, et al., 2009).

Literature Review:
Randomized controlled trials data are lacking regarding the safety and effectiveness of absolute ethanol injection compared to standard therapy for the treatment of BPH. Two small prospective nonrandomized studies without comparators and a case series study totaling 123 patients demonstrated improvements in International Prostate Symptom Score (IPSS), quality of life scores, and significant differences in peak flow volumes and post void residual after therapy (Arslan, et al., 2014; Sakr, et al., 2009; Magno, et al., 2008).

High-Intensity Focused Ultrasound (HIFU): High-intensity focused ultrasound (HIFU) is a procedure which uses a small probe to produce bursts of ultrasound that creates coagulation necrosis in a specific area of tissue. Frequencies range from 4–10 MHz, although 4 MHz is most frequently used. HIFU devices use imaging ultrasound for treatment planning and monitoring, and they deliver targeted high-intensity ultrasound that rapidly elevates the temperature in a precise focal zone. The increased tissue temperature is designed to kill excess prostate tissue (in the case of BPH). The same probe can be used for imaging, which allows both diagnostic and therapeutic testing at the same time.

Literature Review:
Randomized controlled trials are lacking in the published peer reviewed literature regarding the safety and effectiveness of HIFU for the treatment of BPH. Existing literature is limited to a single systematic review and meta-analysis of 12 single-arm studies without a control group.

Garcia-Becerra et al. (2024) conducted a systematic review and meta-analysis of 12 single-arm studies (6 experimental, 6 observational) without control groups to assess the safety and efficacy of high-intensity focused ultrasound (HIFU) as a non-invasive treatment for benign prostatic hyperplasia (BPH). The analysis included 522 participants. Inclusion criteria required peer-reviewed studies with >10 participants using ultrasound-guided HIFU for BPH, and reporting both pre- and post-treatment outcomes. Exclusion criteria included abstracts, editorials, reviews, case reports or series with <10 participants, studies using non-transrectal ultrasound guidance, or lacking follow-up data. Primary outcomes included peak urinary flow rate (Qmax), International Prostate Symptom Score (IPSS), postvoid residual volume (PVR), prostate volume, and catheterization time. Secondary outcomes were treatment duration and follow-up length. Follow-up ranged from 1 to 12 months. HIFU was associated with clinically significant improvements in Qmax, IPSS, and PVR across all follow-up periods. Reported complications included transient hematuria, hematospermia, and urinary retention. Post-treatment transurethral resection of the prostate (Pt-TURP) was required in 50% of cases (n=261), infections occurred in 25% (n=130), enterovesical fistulas in 16.7% (n=87), and stenosis in 8.3% (n=43). Limitations noted by the authors included lack of randomization, blinding, and control groups. Additional limitations included a potential conflict of interest and short-term follow-up.

Histotripsy: Histotripsy is an extracorporeal ultrasound technology that has been proposed to treat BPH. Histotripsy is a form of focused ultrasound therapy that utilizes cavitational mechanisms to produce tissue necrosis in prostatic tissue.

Literature Review:
There are scarce data in the published peer-reviewed scientific literature to support the safety and effectiveness of histotripsy for the treatment of BPH. At this time the role of this therapy has not yet been established (Schuster et al., 2018; Lusuardi, et al., 2013; Hempel, et al., 2011).

Temporary implantable nitinol device (TIND): A TIND is a device proposed to provide a minimally invasive means of increasing prostatic urethral patency to relieve the symptoms of urinary outflow obstruction secondary to benign prostatic hypertrophy (BPH). The TIND is crimped and delivered through a cystoscope sheath, and then, when placed in the urethra, it is released from the cystoscope sheath to assume its expanded configuration, thereby reshaping the urethra and the bladder neck. It is removed after a few days under local anesthesia. (Magistro, et al., 2017; Marcon, et al., 2018; Nickels, et al., 2018; Porpiglia, et al., 2015).

Food and Drug Administration (FDA):
In 2020, the FDA granted a de novo classification clearance (DEN190020) for the iTind System (Medi-Tate Ltd, Or Akiva, IL). The system was classified as a temporarily placed urethral opening system for symptoms of benign prostatic hyperplasia. According to the FDA summary document, the iTind System "is intended for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men age 50 and above." The self-expanding implant is deployed at the bladder neck between the obstructed prostatic lobes by means of a pre-mounted device on a dedicated guide wire. The implant provides continuous pressure for 5–7 days and is removed using a Foley catheter. In June 2021, the iTind System (Medi-Tate Ltd, Philadelphia, PA) received FDA 510(k) approval (K210138) using the prior version as the predicate device. Indications for use were unchanged.

Literature Review:
There are limited data in the published peer-reviewed scientific evidence to determine the safety and efficacy of the TIND as a treatment option for BPH. The existing literature includes narrative and systematic reviews, a single randomized controlled trial, and a network meta-analysis that are

limited by small sample sizes, short-term follow-up, lack of direct comparisons, and heterogeneity in study design.

ECRI (2023) completed a clinical evidence assessment of two systematic reviews with narrative analysis (n=481), two systematic reviews with meta-analysis (n=4832), and one randomized controlled trial (RCT) (n=175) to evaluate the safety and efficacy of the iTIND system for the treatment of BPH. The RCT reported a mean age of 61.1 years. ECRI included systematic reviews or comparative studies that evaluated first- or second-generation iTIND devices in men with BPH and reported on patient-oriented outcomes (i.e., lower urinary tract symptoms, quality of life (QOL), sexual function). Less comprehensive studies or systematic reviews with overlapping patients were excluded. Comparators utilized in the studies included were before and after treatment, transurethral resection of the prostate (TURP), and minimally invasive treatments (i.e., Rezum, Aquablation, prostatic urethral lift, prostatic arterial embolization, transurethral microwave thermotherapy). Among the studies included, follow-up ranged from three months to three years. The single RCT in the assessment utilized a three-month follow-up. ECRI reported significant improvements or neutrality in International Prostatic Symptoms and QOL scores and no change in sexual function compared to TURP, Rezum, PUL, PAE, and transurethral microwave thermotherapy. Most reported adverse events were classified as "mild" to "moderate" and included: urinary retention, urinary tract infection, and sepsis. No new cases of erectile dysfunction were identified. Serious" adverse events were <10%. Complication rates ranged from 1.4–2.3% and surgical retreatment rate was reported as 8.6%. ECRI noted limitations included: the small number of studies evaluating iTIND, lack of RCTs, high risk of bias, and short-term follow-up. Additional limitations include incomplete data reporting among individual studies. ECRI stated that larger RCTs reporting on patient-oriented outcomes with longer follow-up (i.e., ≥5 years) are needed to address the evidence gaps.

Chughtai et al. (2021) conducted a randomized controlled trial to evaluate the safety and efficacy of the iTind system on lower urinary tract symptoms (LUTS) in men with benign prostatic hyperplasia. A total of 175 men with a mean age of 61.1 years were randomized 2:1 and assigned to either treatment with iTind (n=118) or sham control (n=57). Criteria for inclusion were as follows: men ≥ 50 years, International Prostate Symptoms Score (IPSS) ≥ 10; peak urinary flow rate (PFR) ≤ 12 mL/sec with a 125 mL voided volume; prostate volume between 25–75c; and a normal urinalysis, CBC, and biochemistry. Participants were excluded if they had: a post void residual volume (PVR) > 250 mL, an obstructive median lobe (OML), prostate specific antigen (PSA) > 10 ng/mL or free PSA < 25% without a subsequent negative prostate biopsy, previous prostate surgery, prostate or bladder cancer, neurogenic bladder and/or sphincter abnormalities, or confounding bladder pathologies based on medical history, recent cystolithiasis or hematuria, active urinary tract infection, compromised renal function, severe respiratory disorders, known immunosuppression, active antithrombotic or antiplatelet treatment, or cardiac disease including arrhythmias and uncontrolled diabetes mellitus. The intervention consisted of the implantation of the iTind system which was then removed after five to seven days. Sham served as the comparator which consisted of the insertion and removal of an 18F silicon Foley catheter to simulate insertion and removal of the iTind system. The primary outcome measured was the percentage of patients achieving a three-point reduction in IPSS at three months. Quality of life (QoL), PFR, PVR, and sexual function served as secondary outcomes. Follow-up occurred at 6 weeks, three months, and twelve months. At least a three-point significant reduction in IPSS at three months was observed in 78.6% of participants who received the iTind procedure compared to 60% of participants in the control arm (p=0.029). Overall, non-significant improvement of IPSS was observed in the iTind group by an average of 9 points compared to 6.6 points in the sham group (p=0.63). Non-significant improvement in QoL, PFR, and PVR scores were observed in the intervention group compared to the control group (p=0.264, p=0.230, p=0.781, respectively). There was no change in sexual function according to questionnaires. Significant improvement in IPSS in the intervention group was maintained at 12 months. Adverse events in the intervention

group included: urinary retention (n=2), UTI (n=2), and sepsis (n=1). These adverse events did not occur in the control group. Author noted limitations included: loss to follow-up of 29% of patients in the intervention group and 30% in the control group and an inability to generalize the results to all men with LUTS due to BPH due to specific inclusion criteria. Additional limitations of the study include the small patient population and short-term follow-up.

Porpiglia et al. (2019) conducted a prospective single-arm, multicenter study (n=81) to assess the feasibility, safety and efficacy of a second-generation of temporary implantable nitinol device (iTIND; Medi-Tate Ltd, Or-Akiva, Israel) for the treatment of lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH). The mean age of participants was 65 years. The inclusion criteria were: LUTS, International Prostate Symptom Score (IPSS) ≥10, maximum urinary flow rate (Qmax) ≤12 mL/s, and prostate volume <75 mL. The exclusion criteria were: hemostatic disorders, neurogenic bladder and/or sphincter abnormalities, impaired renal function, history of urethral strictures, post-void residual urine volume (PVR) >250 mL, urinary bladder stones, bladder cancer, obstructive median lobe, active UTI, and previous prostate surgery. After discontinuation of pharmacological therapy, patients underwent implantation of the iTIND within the bladder neck and the prostatic urethra under light sedation. The device was removed five to seven days later. There were no comparators in this single arm study. The outcome measures were maximum urinary flow rate (Qmax), International Prostate Symptom Score (IPSS), quality of life (QoL), and post-void residual urine volume (PVR). Follow-up was conducted at one, three, six, and 12 months postoperatively. Statistical significance was shown with an improvement in Qmax from a baseline of 7.3 ml/s to 11.2 ml/s at one month, 12.4 ml/s at three months, 13.69 ml/s at six months, and 14.7 ml/s at one year follow up ($p<0.001$); an improvement in total IPSS from a baseline of 26.22 to 13.81 at one month, 11.61 at three months, 11.57 at six months, and 10.38 at one year ($p<0.001$); an improvement in QoL from a baseline of 4 to two at one, three, and six months, and one at one year follow up ($p<0.001$); and an overall improvement in PVR from a baseline of 76.17 mL to 49.84 mL at one month, 46.75 mL at three months, 48.84 mL at six months, and 34.03 at one year follow up ($p<0.001$). The authors reported a 5% treatment failure rate (n=4). At 48-month follow-up, Amparore et al. (2023) reported that clinically significant improvements in QoL and IPSS scores remained ($p<0.001$). Surgical re-treatment rates were 8.6% at ≤36 months and 4% at >36 months. Adverse events included: hematuria, urinary urgency, urinary retention, pain, dysuria, and UTI. Author noted limitations of the study include: short term follow-up, lack of a control, selection bias, and participant attrition.

Transrectal Thermal Therapies: There are scarce data in the published peer-reviewed scientific evidence to determine the safety and efficacy of thermal therapy via the rectum as a treatment option for BPH. At this time the role of this therapy has not yet been established.

Transurethral Balloon Dilation of the Prostatic Urethra: Transurethral balloon dilation of the prostatic urethra, also known as endoscopic balloon dilation of the prostatic urethra, involves the insertion of a balloon catheter through the urethra into the prostatic urethra where it is inflated to stretch the urethra where it has been narrowed by the prostate.

Literature Review:
There are scarce data regarding the safety and effectiveness of this therapy for the treatment of BPH and its role has not yet been established.

Water-Induced Thermotherapy (WIT): WIT is a minimally invasive therapy that uses hot water circulating through a urethral balloon catheter to deliver heat energy to prostate tissue and thereby shrink the prostate and treat symptoms of BPH. It is generally considered only for patients who cannot undergo TURP or who require less invasive treatments, however the long-term safety and effectiveness of this treatment in this or other proposed subsets of individuals has not been proven.

U.S. Food and Drug Administration (FDA):
The AquaTherm device, formerly known as the Thermoflex™ Water-Induced Thermotherapy System (ACMI, Southborough, MA, previously Argomed, Inc., Cary, NC) (K000508) is a catheter-based thermal therapy device for the treatment of symptoms due to urinary outflow obstruction secondary to BPH. FDA 510(k) class II approval was received in 1999.

Literature Review:
There is insufficient evidence in the existing peer-reviewed literature to establish the safety and efficacy of WIT for the treatment of BPH. Evidence is limited to data that lack direct comparisons to established treatments such as transurethral resection of the prostate (TURP) or pharmacologic therapy. Furthermore, the data on adverse effects are missing. Additionally, optimal treatment protocols have not been standardized, limiting reproducibility and generalizability.

Minardi et al. (2004) reported that WIT resulted in a reduction of prostatic volume of 5.2% compared with a decrease of 48.4% when transurethral resection of the prostate (TURP) was performed. The urine flow rate increased more after TURP (75.3%) than after WIT (16.7%). Residual prostate volume decreased more after TURP (89.8%) than after WIT (25.2%), an increase of maximum flow rate of 16.7% and a decrease of residual volume of 25.2%. The relief of bladder outlet obstruction was indicated by the decrease of detrusor pressure at maximum flow rate in comparison to baseline values; decreases of 27.5% were noted for WIT compared with decreases of 48% for transurethral resection of the prostate (TURP).

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD		No Determination found	
LCD		No Determination found	

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

Coding Information

Notes:
1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare and Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Not Medically Necessary for the treatment of benign prostatic hyperplasia (BPH):

CPT®* Codes	Description
53865	Cystourethroscopy with insertion of temporary device for ischemic remodeling (ie, pressure necrosis) of bladder neck and prostate
53899	Unlisted procedure, urinary system
55899	Unlisted procedure, male genital system
76999	Unlisted ultrasound procedure (eg, diagnostic, interventional)

CPT®* Codes	Description
53865	Cystourethroscopy with insertion of temporary device for ischemic remodeling (ie, pressure necrosis) of bladder neck and prostate
0950T	Ablation of benign prostate tissue, transrectal, with high intensity–focused ultrasound (HIFU), including ultrasound guidance

HCPCS Codes	Description
C9769	Cystourethroscopy, with insertion of temporary prostatic implant/stent with fixation/anchor and incisional struts (Code deleted 12/31/2024)

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Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	• No clinical policy statement changes.	9/15/2025
Focused Review	• No clinical policy statement changes.	2/15/2025
Focused Review	• Removed policy statement for prostate artery embolization	11/1/2024
Annual Review	• Removed policy statements for Urethral lift (e.g., UroLift), Water vapor thermal therapy (e.g., Rezūm System), and Waterjet tissue ablation (e.g., AquaBeam System).	9/15/2024