Medical Coverage Policy

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Coverage Policy Number..... 0159

Benign Prostatic Hyperplasia (BPH) Surgical Treatments

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Related Coverage Resources

Botulinum Therapy
High Intensity Focused Ultrasound (HIFU)
Pulmonary Arterial Hypertension – Phosphodiesterase Type 5 Inhibitors

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 is the most common prostate problem for men older than age 50. In 2010, as many as 14 million men in the United States had lower urinary tract symptoms suggestive of benign prostatic hyperplasia. Although benign prostatic hyperplasia rarely causes symptoms before age 40, the occurrence and symptoms increase with age. Benign prostatic hyperplasia affects about 50 percent of men between the ages of 51 and 60 and up to 90 percent of men older than 80 (National Institutes of Diabetes and Digestive and Kidney Diseases (NIDDK, 2014).

According to a 2020 press release from the American Urological Association (AUA), "race and ethnicity are observed as significant factors associated with disparate higher incidence and poorer outcomes" for BPH. The AUA cited a retrospective cohort study in which information was collected on age, race, ethnicity, primary insurance, and rural-urban commuting area for patients presenting to Florida emergency departments with reports of lower urinary tract symptoms and acute urinary retention. The study found that men aged 45 years and older were more likely to be of non-white race, have Medicare or private insurance, and live in more urbanized areas. The authors concluded that "African-American and Hispanic patients may be untreated or undertreated for BPH in the outpatient setting". However, data specifically addressing the prevalence of BPH by race/ethnicity are limited and conflicting.

Antoine, et al. (2022) conducted a retrospective review of regional hospital network database information from the University of Colorado Health from January 2011 – October 2018 to determine if race and ethnicity are associated with the likelihood of undergoing surgical treatment for BPH. Male patients (n=30,466) were included in the review if their electronic medical records or billing data showed that they were over the age of 40, on medical therapy for lower urinary tract symptoms (LUTS) associated with BPH, and that they had had two or more provider visits for this diagnosis. The race/ethnicity of the study population consisted of white (n=24,443; 80.2%), Hispanic (n=2715; 8.9%), Black/African American (n=1245; 4.1%), and other race/ethnicity (2073; 6.8%). After adjusting for age, insurance status, major comorbidities, and type of LUTS medication, the authors found that Black/African American patients were significantly less likely than white patients to have been treated with surgery (p=0.011). Similar results were found for individuals who self-identified as other race/ethnicity (p=0.013). The authors postulated that this disparity may be due to implicit bias on the part of the providers, patient differences in attitudes toward medical care, or other structural factors. A limitation of this study is that it is not generalizable to the Black male population in the United States.

In a retrospective cohort study of newly diagnosed Medicare beneficiaries with BPH, Narang et al. (2023) evaluated Medicare claims data from 2009 through 2019 to determine if race has an impact on BPH surgical treatment rates. All eligible beneficiaries with a diagnosis of BPH were followed from their earliest BPH diagnosis until their earliest claim date for BPH surgery, prostate or bladder cancer diagnosis, the end of their continuous enrollment, death, or the end of the study period and were then divided by race (i.e., White or Black, Indigenous, and People of Color (BIPOC)). The median follow-up time was 3.6 years for White men and 2.8 years for BIPOC men. Key outcomes for this study included the type of BPH surgery (i.e., minimally invasive or invasive), time to surgery, and site of surgery. There were 31,699 beneficiaries included in the study, 86.3% were White (n=27,368), and 13.7% were BIPOC (n=4331). A total of 1853 beneficiaries underwent BPH surgery. TURP was the most common surgery type for both groups. BIPOC men were more likely to undergo TURP than White men (p=0.052). BIPOC men had significantly lower BPH surgical rates than White men (p=0.002) by the end of the study period. After controlling for geographical region of residence and comorbidities, BIPOC race was associated with a 19% significantly lower likelihood of receiving BPH surgery than White race (p=0.005). For those men who underwent surgery, BIPOC men were significantly more likely to undergo surgery in an inpatient setting compared to White men (p<0.001). There were no significant differences reported between groups for type of surgical procedure and race. Author reported limitations of the study included: claims data that does not include potential confounders (e.g., physician/patient preferences, symptom severity, medication adherence, socioeconomic and environment factors), potential coding errors, and inability to generalize Medicare claims data to the general population.

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, 2019; Dixon, et al., 2015b, 2016; Perera, et al., 2015; Sønksen, et al., 2015; Cantwell, et al., 2014; McVary, et al., 2014, 2016a, 2021; Shore, et al., 2014; McNicholas, et al., 2013; Roehrborn, et al., 2013, 2015a, 2015b, 2016, 2017a, 2017b; Barkin, et al., 2012; Chin, et al., 2012; Woo, et al., 2011, 2012). 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:
There are scarce data in the published peer-reviewed scientific literature regarding the safety and effectiveness of HIFU for the treatment of BPH.

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 (FDA, 2020a). 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 (FDA, 2021b).

Literature Review:
There are scarce data in the published peer-reviewed scientific evidence to determine the safety and efficacy of the TIND as a treatment option for BPH.

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). 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 patient 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 are scarce data in randomized controlled clinical trials or comparative studies regarding outcomes of WIT as a treatment for BPH. 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).

Currently there is insufficient evidence in the peer-reviewed scientific evidence to determine the safety and effectiveness of WIT for the treatment of BPH. Additionally, there is insufficient direct comparison of WIT to other treatment options for BPH; optimal protocols have not been established and long-term information regarding duration of treatment effect or adverse effects is lacking.

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	No National Coverage Determination found	
LCD	CGS	Fluid Jet System in the Treatment of Benign Prostatic Hyperplasia (BPH) (L38378)	10/22/2023
LCD	CGS	Laser Ablation of the Prostate (L34090)	3/23/2023
LCD	NGS	Fluid Jet System in the Treatment of Benign Prostatic Hyperplasia (BPH) (L38367)	11/1/2020
LCD	NGS	WATER VAPOR Thermal Therapy for LUTS/BPH (L37808)	4/1/2023
LCD	First Coast	Transurethral Waterjet Ablation of the PROSTATE (L38726)	12/27/2020
LCD	Noridian	Transurethral Waterjet Ablation of the PROSTATE (L38705)	12/27/2020
LCD	Novitas	Transurethral Waterjet Ablation of the PROSTATE (L38712)	12/27/2020
LCD	Palmetto	Transurethral Waterjet Ablation of the PROSTATE (L38549)	1/29/2023
LCD	Wisconsin Physicians Service	Transurethral Waterjet Ablation of the PROSTATE (L38682)	10/15/2023

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
53899	Unlisted procedure, urinary system
55880	Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound (HIFU), including ultrasound guidance
55899	Unlisted procedure, male genital system
76999	Unlisted ultrasound procedure (eg, diagnostic, interventional)

HCPCS Codes	Description
C9769	Cystourethroscopy, with insertion of temporary prostatic implant/stent with fixation/anchor and incisional struts

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Revision Details

Type of Revision	Summary of Changes	Date
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
Annual Review	• Title change. • Removed policy statement for: cryosurgical ablation, interstitial laser coagulation (ILC), plasma kinetic vaporization (e.g., PlasmaKinetic™ Tissue Management System), transperineal laser ablation (TPLA) (e.g., SoracteLite), and transurethral ultrasound-guided laser incision of the prostate (TULIP).	12/15/2023