



BlueCross BlueShield
of Alabama

Name of Blue Advantage Policy:

Treatment of Benign Prostatic Hyperplasia

Policy #: 725

Latest Review Date: February 2024

Category: Medical

BACKGROUND:

Blue Advantage medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
 - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
 - *Furnished in a setting appropriate to the patient's medical needs and condition;*
 - *Ordered and furnished by qualified personnel;*
 - *One that meets, but does not exceed, the patient's medical need; and*
 - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000, which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill **Original Medicare for covered services that are related to **clinical trials** that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Effective for dates of service August 15, 2024, and after:

For **Transurethral Waterjet Ablation of the Prostate**, refer to L38549 and A58008

For **Cryosurgery of Prostate**, refer to NCD 230.9

Blue Advantage will treat the following treatments for benign prostatic hyperplasia as a **covered benefit** as a second-line treatment when medication is ineffective or there is an immediate need for intervention:

- BPH Catheter System (Optilume®)
- Drug-Coated Balloon catheter system (Optilume®)
- Holmium laser procedures of the prostate (HoLAP, HoLEP, HoLRP)
- Laser Transurethral Enucleation of the Prostate (TUEP)
- Laser Transurethral Vaporization of the Prostate (TUVF)
- Prostate artery embolization of the prostate
- PVP (Photoselective Laser Vaporization)
- Rezum (water vapor thermotherapy)
- Temporarily Implanted Nitinol Device (iTind™ System)
- Transurethral guided Laser Induced Prostatectomy (TULIP)
- Transurethral Incision of the Prostate (TUIP)
- Transurethral Microwave Thermography (TUMT)
- Transurethral Needle Ablation (TUNA)
- Visually guided Laser Ablation of the Prostate (VLAP)

Blue Advantage will treat the following treatments for benign prostatic hyperplasia as a **non-covered benefit** and as investigational, including but not limited to:

- Absolute ethanol injection
- Balloon dilation of the prostate
- Temporary Prostatic Stent
- Transurethral Plasmakinetic Resection of the Prostate (PKRP)
- Water-induced thermotherapy

Effective for dates of service March 1, 2024, through August 14, 2024:

For **Transurethral Waterjet Ablation of the Prostate**, refer to L38549 and A58008

For **Cryosurgery of Prostate**, refer to NCD 230.9

Blue Advantage will treat the following treatments for benign prostatic hyperplasia as a **covered benefit** as a second-line treatment when medication is ineffective or there is an immediate need for intervention:

- Holmium laser procedures of the prostate (HoLAP, HoLEP, HoLRP)
- Laser Transurethral Enucleation of the Prostate (TUEP)
- Laser Transurethral Vaporization of the Prostate (TUVF)
- Prostate artery embolization of the prostate

- PVP (Photoselective Laser Vaporization)
- Rezum (water vapor thermotherapy)
- Transurethral guided Laser Induced Prostatectomy (TULIP)
- Transurethral Incision of the Prostate (TUIP)
- Transurethral Microwave Thermography (TUMT)
- Transurethral Needle Ablation (TUNA)
- Visually guided Laser Ablation of the Prostate (VLAP)

Blue Advantage will treat the following treatments for benign prostatic hyperplasia as a **non-covered benefit** and as investigational, including but not limited to:

- Absolute ethanol injection
- Balloon dilation of the prostate
- Temporary Prostatic Stent
- Transurethral Plasmakinetic Resection of the Prostate (PKRP)
- Water-induced thermotherapy
- Temporarily Implanted Nitinol Device (iTind™ System)

Effective for dates of service prior to March 1, 2024:

For **Transurethral Waterjet Ablation of the Prostate**, refer to L38549 and A58008

For **Cryosurgery of Prostate**, refer to NCD 230.9

Blue Advantage will treat the following treatments for benign prostatic hyperplasia as a **covered benefit** as a second-line treatment when medication is ineffective or there is an immediate need for intervention:

- Holmium laser procedures of the prostate (HoLAP, HoLEP, HoLRP)
- iTind
- Laser Transurethral Enucleation of the Prostate (TUEP)
- Laser Transurethral Vaporization of the Prostate (TUVF)
- PVP (Photoselective Laser Vaporization)
- Rezum (water vapor thermotherapy)
- Transurethral guided Laser Induced Prostatectomy (TULIP)
- Transurethral Incision of the Prostate (TUIP)
- Transurethral Microwave Thermography (TUMT)
- Transurethral Needle Ablation (TUNA)
- Visually guided Laser Ablation of the Prostate (VLAP)

Blue Advantage will treat the following treatments for benign prostatic hyperplasia as a **non-covered benefit** and as investigational, including but not limited to:

- Absolute ethanol injection
- Balloon dilation of the prostate
- Prostate artery embolization of the prostate

- Temporary Prostatic Stent
- Transurethral Plasmakinetic Resection of the Prostate (PKRP)
- Water-induced thermotherapy
- Temporarily Implanted Nitinol Device (iTind™ System)

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

Benign prostatic hyperplasia (BPH) is a common condition in older men, affecting to some degree 40% of men in their 50s, 70% of those between ages 60 and 69, and almost 80% of those ages 70 and older.¹ BPH is a histologic diagnosis defined as an increase in the total number of stromal and glandular epithelial cells within the transition zone of the prostate gland. In some men, BPH results in prostate enlargement which can, in turn, lead to benign prostate obstruction and bladder outlet obstruction, which are often associated with lower urinary tract symptoms (LUTS) including urinary frequency, urgency, irregular flow, weak stream, straining, and waking up at night to urinate. Lower urinary tract symptoms are the most commonly presenting urological complaint and can have a significant impact on quality of life.

BPH does not necessarily require treatment. The decision on whether to treat BPH is based on an assessment of the impact of symptoms on quality of life along with the potential side effects of treatment. Options for medical treatment include alpha-1-adrenergic antagonists, 5-alpha-reductase inhibitors, anticholinergic agents, and phosphodiesterase-5 inhibitors. Medications may be used as monotherapy or in combination.

Patients with persistent symptoms despite medical treatment may be considered for surgical treatment. The traditional standard treatment for BPH is transurethral resection of the prostate (TURP). TURP is generally considered the reference standard for comparisons of BPH procedures. Several minimally invasive prostate ablation procedures have also been developed, including transurethral microwave thermotherapy, transurethral needle ablation of the prostate, urethromicroablation phototherapy, and photoselective vaporization of the prostate. The prostatic urethral lift procedure involves the insertion of one or more permanent implants into the prostate, which retracts prostatic tissue and maintains an expanded urethral lumen.

Transurethral water vapor thermal therapy and transurethral waterjet ablation (aquablation) have been investigated as minimally invasive alternatives to transurethral resection of the prostate, considered the traditional standard treatment for benign prostatic hyperplasia. Transurethral water vapor thermal therapy uses radiofrequency-generated water vapor (~103°C) thermal energy based on the thermodynamic properties of convective versus conductive heat transfer to

ablate prostate tissue. Aquablation cuts tissue by using a pressurized jet of fluid delivered to the prostatic urethra.

Temporarily implanted nitinol devices have been proposed as a minimally invasive alternative to transurethral resection of the prostate (TURP), considered the traditional standard treatment for symptomatic benign prostatic hyperplasia. The device is temporarily implanted into the obstructed prostatic urethra to facilitate tissue reshaping and improve urine outflow. The implant is typically removed after 5 to 7 days of treatment.

The Optilume drug-coated balloon offers a minimally invasive treatment option for men suffering from urinary tract conditions like benign prostatic hyperplasia (BPH), and urethral strictures. Urethral strictures are often caused by infections, trauma, and other medical procedures that injure the lining of the urethra. Close to 95-98% of urethral strictures in the United States are treated with endoscopic means, meaning with a dilation or urethrotomy. An open surgical procedure called urethroplasty, another treatment option for urethral stricture, is noted to have a better success rate however, it may require a longer recovery and possible side effects. The Optilume drug-coated balloon is a guidewire compatible catheter with a tapered atraumatic tip. The distal end of the catheter has an inflatable balloon coated with a proprietary coating containing the drug paclitaxel that facilitates the drug's transfer to the urethral wall upon inflation. ECRI (Emergency Care Research Institute) noted in their Clinical Evidence Assessment on Optilume Drug-coated Balloon for Treating Urethral Stricture Disease (2022) that the evidence was inconclusive. The following evidence gaps were noted: Additional double-blind RCTs comparing Optilume with other urethral stricture treatments and reporting on patient-oriented outcomes at longer follow-up times (>2years) are needed to assess Optilume's comparative safety and effectiveness. Three ongoing clinical studies may provide additional data and may partially address evidence gaps

KEY POINTS:

This evidence review has been updated regularly with search of the PubMed database. Most recently, the literature was reviewed through April 17, 2024.

Summary of Evidence

Laser Techniques

There have been multiple studies performed using laser procedures. Generally, these procedures have shown significant improvements in IPSS, QoL score and Qmax. Long-term follow-up with laser procedures has shown results similar to TURP. The evidence is sufficient to determine the effects of these techniques on net health outcomes.

Transurethral Techniques

There have been multiple studies performed using transurethral techniques for BPH. Excellent long-term results have been reported as well as improvements in IPSS, QoL score and Qmax. The evidence is sufficient to determine the effects of these techniques on the net health outcome.

Other Techniques

The evidence for other techniques such as Aquablation, Rezum, balloon dilation, cryoablation, et al consists of RCTs, meta-analyses, single-arm prospective studies, and comparative trials. Most studies are small and do not have long-term data. One industry-sponsored RCT for Rezum with results to 4 years shows promising results, but additional long-term and well-designed randomized controlled studies are needed. Additionally, there is a lack of comparison of these procedures to TURP. The evidence is insufficient to determine the effects of these procedures on net health outcome.

For individuals who have benign prostatic hypertrophy (BPH) and lower urinary tract symptoms (LUTS) who receive transurethral water vapor thermal therapy, the evidence includes one 3-month, sham-controlled, randomized trial of 197 patients with a 5-year uncontrolled follow-up phase and 1 multicenter, prospective, single-arm study. The outcomes of interest are symptoms, functional outcomes, quality of life, and treatment-related morbidity. At 3 months, LUTS improved more in the intervention group compared to the sham procedure. No adverse effects on erectile or ejaculatory function were observed, and improvements were sustained through 5 years of follow-up. The evidence is limited by the small sample size, lack of blinding of longer-term outcomes, and lack of comparison to alternative treatments such as transurethral resection of the prostate (TURP). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have BPH and LUTS who receive aquablation, the evidence includes a single noninferiority randomized controlled trial (RCT) of aquablation compared to TURP in 187 patients with 5 years of follow-up and several multicenter, prospective, single-arm studies. The outcomes of interest are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The primary efficacy endpoint was the difference between groups in the change in International Prostate Symptom Score (IPSS) at 6 months, and the primary safety endpoint was the development of Clavien-Dindo persistent grade 1, or 2 or higher operative complications at 3 months. At 6 months, mean IPSS decreased from baseline by 16.9 points for aquablation and 15.1 points for TURP (mean difference, 1.8 points; $p < .0001$ for noninferiority and $p = .1347$ for superiority). The primary safety endpoint rate was lower in the aquablation group compared to the TURP group (26% vs. 42%; $p = .0149$). The rate of grade 2 and greater events was similar in the 2 groups (20% for aquablation and 23% for TURP; $p = .3038$). Over 5 years, improvements remained similar between groups with no new safety signals. Confidence in these conclusions is reduced due to imprecision of estimates and a lack of additional supportive trials, especially with regard to comparative adverse events. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have benign prostatic hyperplasia (BPH) with lower urinary tract symptoms who receive a temporarily implanted nitinol device (eg, iTind), the evidence includes a meta-analysis, 1 randomized controlled trial (RCT), and 2 single-arm, multicenter, international prospective studies. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, and treatment-related morbidity. One network meta-analysis compared the safety and efficacy of various minimally invasive treatments for lower urinary tract symptoms associated with BPH, finding that iTind may result in worse urologic symptoms scores compared to transurethral resection of the prostate (TURP) at short-term follow-up. One

RCT compared the iTind device with a sham procedure and reported an improvement of at least 3 points on the International Prostate Symptom Score (IPSS) scale at 3 months in 78.6% versus 60% of participants, respectively ($p=.029$). However, corresponding changes in overall IPSS, IPSS quality of life, peak urinary flow rate, Sexual Health Inventory for Men (SHIM), and International Index of Erectile Function scores were not significantly different between groups. One single-arm study reported significant improvements in symptoms and functional outcomes through >4 years. A subsequent single-arm study enrolling men desiring to preserve ejaculatory function reported no significant change in the SHIM total score and a statistically significant improvement on the Male Sexual Health Questionnaire for Ejaculatory Dysfunction questionnaire at 6 months. No studies have directly compared iTind to established alternatives; however, an RCT comparing iTind with the UroLift prostatic urethral lift procedure is currently ongoing. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Data from one RCT and one single-arm study suggest that the Optilume BPH Catheter System may improve peak urinary flow rate and symptoms associated with benign prostatic hyperplasia, but symptom scores did not reach statistical significance in the RCT. There are multiple limitations of the data including lack of control group in one study, concerns about serious adverse events (hematuria was most common), and the treatment may not be generalizable for prostates above 80g. Long-term follow-up is also needed to determine durability of this treatment. No studies have directly compared the Optilume BPH Catheter System to established treatments. There is also a lack of data on paclitaxel in tissues at long-term follow-up. There is not yet enough evidence that the technology results in an improvement in the net health outcome. Data from one RCT and two single-arm studies reported that the Optilume Urethral Drug-Coated Balloon significantly reduced stricture recurrence, increased urinary flow rate, and improved urinary symptom scores. The RCT reported significantly greater improvement with the drug-coated balloon than with endoscopic management. Drug-coated balloon treatment was more durable than endoscopic treatment at one-year follow-up. Limitations of the RCT are that most participants had bulbar urethral strictures, so it is unknown whether the treatment is generalizable to all types of urethral strictures; hematuria was more common with the drug-coated balloon; and this treatment has not been compared to urethroplasty which is most successful for treating recurrent strictures. In these studies, long-term follow-up beyond one year occurred only in small single-arm studies. Further, additional long-term data on paclitaxel in tissues is needed to assess device safety. There is not yet enough evidence that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

American Urological Association

In 2021, the American Urological Association published guidelines on the surgical evaluation and treatment of lower urinary tract symptoms (LUTS) attributed to benign prostatic hyperplasia (BPH). An amendment to these guidelines was published in 2023. The following recommendations are related to the interventions included in this evidence review:

- Water vapor thermal therapy should be considered as a treatment option for patients with LUTS/BPH provided prostate volume is 30 to 80 g. (Moderate Recommendation; Evidence Level: Grade C)

- Water vapor thermal therapy may be offered as a treatment option to eligible patients who desire preservation of erectile and ejaculatory function. (Conditional Recommendation; Evidence Level: Grade C)
- Robotic waterjet treatment may be offered as a treatment option to patients with LUTS/BPH provided prostate volume is 30 to 80 g. (Conditional Recommendation; Evidence Level: Grade C)

In 2021, the American Urological Association (AUA) published guidelines on the surgical evaluation and treatment of lower urinary tract symptoms (LUTS) attributed to benign prostatic hyperplasia (BPH). These guidelines do not address the use of temporarily implanted nitinol devices.

A 2023 amendment to the 2021 AUA guideline stated that temporary implanted prostatic devices are an option for individuals with BPH, LUTS, prostate volume of 25 to 75 grams, and who lack an obstructive median lobe. This recommendation was based on expert opinion due to an absence of sufficient evidence.

National Institute for Health and Care Excellence

In 2020, the NICE issued the following guidance on Rezum for treatment of LUTS secondary to BPH:

"Evidence supports the case for adopting Rezum for treating lower urinary tract symptoms (LUTS) caused by benign prostatic hyperplasia (BPH) in the NHS [National Health Service]. Rezum relieves LUTS and improves quality of life."

"Rezum is a minimally invasive procedure. It should be considered as a treatment option for people with:

- moderate to severe LUTS (International Prostate Symptoms Score [IPSS] typically 13 or over) and
- a moderately enlarged prostate (typically between 30 cm³ and 80 cm³)."

In 2023, NICE updated guidance on transurethral water jet ablation for LUTS caused by BPH. The following recommendations were made:

"Transurethral water jet ablation for lower urinary tract symptoms caused by benign prostatic hyperplasia may be used if standard arrangements are in place for clinical governance, consent, and audit. For auditing the outcomes of this procedure, the main efficacy and safety outcomes identified in this guidance can be entered into NICE's interventional procedure outcomes audit tool (for use at local discretion)."

In 2022, the National Institute for Health and Care Excellence (NICE) issued an interventional procedures guidance on prostatic urethral temporary implant insertion for lower urinary tract symptoms caused by BPH. The recommendation noted that the evidence on the use of these devices is limited in quantity and quality. Therefore, the procedure should only be used with special arrangements for clinical governance, consent, and audit or research.

A Medtech innovation briefing was released by NICE in January 2023 but guidance specific to Aquablation is awaiting development.

The National Institute for Health and Care Excellence noted in their Medtech innovation briefing on Optilume for anterior urethral strictures (2021):

- The main points from the evidence summarised in this briefing are from 1 single-arm prospective study including a total of 53 men. It shows that Optilume is safe for treating urethral strictures, and early 2-year efficacy results are encouraging.
- Key uncertainties around the evidence or technology are that there are no comparative studies, the evidence has limited applicability to the NHS [National Health Service], and longer-term evidence is needed for Optilume, including the effect of paclitaxel on the tissues.

In 2023, the American Urologic Association published an amendment to the 2016 clinical guidelines for management of urethral stricture disease. The AUA added this statement:

Surgeons may offer urethral dilation or direct visual internal urethrotomy, combined with drug-coated balloons, for recurrent bulbar urethral strictures <3cm in length. (Conditional Recommendation; Evidence Level: Grade B) A Conditional Recommendation with Evidence Level B is defined as “Benefits equal to risks/burdens; best action appears to depend on individual patient circumstances; better evidence could change confidence.”

U.S. Preventive Services Task Force Recommendations

Not applicable.

KEY WORDS:

Prostate BPH, aquablation, waterjet ablation, balloon dilation of the prostate, cryoablation, rezum, temporary prostatic stents, transurethral plasmakinetic resection, PKRP, waterjet, water-induced thermotherapy, water vapor thermotherapy, prostatic arterial embolization, artery embolization of the prostate, prostatic ethanol injection, Transurethral Microwave Thermography, TUMT, Transurethral Needle Ablation, TUNA, Laser Transurethral Enucleation of the Prostate, TUEP, Laser Transurethral Vaporization of the Prostate, TUVF, Transurethral guided Laser Induced Prostatectomy, TULIP, PVP, Photoselective Laser Vaporization, Visually guided Laser Ablation of the Prostate, VLAP, Transurethral Incision of the Prostate, TUIP, Transurethral Water Vapor Thermal Therapy, iTind™ System, Temporarily Implanted Nitinol Device, Optilume, Echolaser, Elesta, SoracteLite Transperineal laser ablation, TPLA.

APPROVED BY GOVERNING BODIES:

Multiple instruments including energy-delivery devices employing microwave, radiofrequency, electrical, laser energy, and bipolar plasmakinetic electrovaporization for ablative and vaporization applications; balloons; and stents have received FDA approval.

The Spanner™ temporary prostatic stent received approval from the U.S. Food and Drug Administration (FDA) on December 14, 2006, through the premarket approval or PMA process. 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.”

The Rezum System (NxThera, Inc.) received FDA 510(k) designation on August 27, 2015. In February 2018, the 510(k) was renewed and approved intended to relieve symptoms, obstructions, and reduce prostate tissue associated with BPH. It is indicated for men ≥ 50 years of age with a prostate volume $\geq 30\text{cm}^3$ and $\leq 80\text{cm}^3$. The Rezūm System is also indicated for treatment of prostate with hyperplasia of the central zone and/or a median lobe.

In June 2017, The FDA granted a de novo classification to the intravascular implant, Embosphere Microspheres (BioSphere Medical, S.A., France), as a class II biocompatible PAE device for use as a minimally invasive treatment for symptomatic BPH.

The FDA granted 510(k) approval (K181510) in 2018 for the Echolaser X4 device (El.En Electronic Engineering Spa, Calenzano, Italy) which is “intended for use in cutting, vaporization, ablation and coagulation of soft tissue in conjunction with endoscopic equipment (including laparoscopies, hysteroscopes, bronchoscopes, gastroscopes, cystoscopes and colonoscopies), in incision/excision, vaporization, ablation and coagulation of soft tissue in contact and non-contact open surgery (with or without a hand piece), and in the treatment and/or removal of vascular lesions (tumors)” (FDA, 2018b). The SoracteLite is the Echolaser thermal ablation device proposed for the treatment of urological disorders including BPH.

In April 2019, the iTind System (Olympus; previously, Medi-Tate Ltd., Hadera, Israel) was granted a de novo 510(k) classification by the U.S. Food and Drug Administration (FDA) (DEN190020; product code: QKA). The new classification applies to this device and substantially equivalent devices of this generic type (eg, K210138). The iTind System is intended for the treatment of symptoms due to urinary outflow obstruction secondary to BPH in men aged 50 and older.

In December 2021, the FDA approved the Optilume Urethral Drug Coated Balloon (DCB) through the premarket approval application (PMA) process to be used to treat patients with obstructive urinary symptoms associated with anterior urethral stricture. The device is designed to be used in adult males for urethral stricture of ≤ 3 cm in length.

In June 2023, the Optilume BPH Catheter System (Urotronic, Inc.) received premarket approval by the U.S. FDA (P220029; product code: QXB). The Optilume BPH Catheter System is indicated for the treatment of obstructive urinary symptoms associated with BPH in males age 50 years and older.

BENEFIT APPLICATION:

Coverage is subject to member’s specific benefits. Group-specific policy will supersede this policy when applicable.

CURRENT CODING:**CPT Codes:**

37243	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural road mapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction (for prostatic arterial embolization)
52450	Transurethral incision of prostate
52601	Transurethral electrosurgical resection of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included)
52630	Transurethral resection; residual or regrowth of obstructive prostate tissue including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included)
52647	Laser coagulation of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included if performed)
52648	Laser vaporization of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, internal urethrotomy and transurethral resection of prostate are included if performed)
52649	Laser enucleation of the prostate with morcellation, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, internal urethrotomy and transurethral resection of prostate are included if performed)
52284	Cystourethroscopy, with mechanical urethral dilation and urethral therapeutic drug delivery by drug-coated balloon catheter for urethral stricture or stenosis, male, including fluoroscopy, when performed
53850	Transurethral destruction of prostate tissue; by microwave thermotherapy
53852	Transurethral destruction of prostate tissue; by radiofrequency thermotherapy
53854	Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy

53855	Insertion of a temporary prostatic urethral stent, including urethral measurement
53899	Unlisted procedure, urinary system
55873	Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring)
0421T	Transurethral waterjet ablation of prostate, including control of post-operative bleeding, including ultrasound guidance, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included when performed)
0619T	Cystourethroscopy with transurethral anterior prostate commissurotomy and drug delivery, including transrectal ultrasound and fluoroscopy, when performed
0714T	Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance; prostate volume less than 50 mL
0867T	Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance; prostate volume greater or equal to 50 mL

REFERENCES:

1. Aagaard MF, Niebuhr MH, Jacobsen JD, et al. Transurethral microwave thermotherapy treatment of chronic urinary retention in patients unsuitable for surgery. *Scand J Urol*. 2014 Jun;48(3):290-4.
2. Abdul-Muhsin HM, Jakob NJ, McLemore RM, et al. Infectious complications associated with the use of temporary prostatic urethral stents in patients with benign prostatic hyperplasia. *Can J Urol*. 2016 Oct;23(5):8465-8470.
3. American Urological Association Benign Prostatic Hyperplasia: Surgical Management of Benign Prostatic Hyperplasia/Lower Urinary Tract Symptoms, 2021. Available at: [www.auanet.org/guidelines/guidelines/benign-prostatic-hyperplasia-\(bph\)-guideline](http://www.auanet.org/guidelines/guidelines/benign-prostatic-hyperplasia-(bph)-guideline).
4. Amparore D, Fiori C, Valerio M, et al. 3-Year results following treatment with the second generation of the temporary implantable nitinol device in men with LUTS secondary to benign prostatic obstruction. *Prostate Cancer Prostatic Dis*. Jun 2021; 24(2): 349-357.
5. Amparore D, De Cillis S, Volpi G, et al. First- and Second-Generation Temporary Implantable Nitinol Devices As Minimally Invasive Treatments for BPH-Related LUTS: Systematic Review of the Literature. *Curr Urol Rep*. Jul 05 2019; 20(8): 47.
6. Amparore D, De Cillis S, Schulman C, et al. Temporary implantable nitinol device for benign prostatic hyperplasia-related lower urinary tract symptoms: over 48-month results. *Minerva Urol Nephrol*. Dec 2023; 75(6): 743-751.

7. Arslan M, Ozturk A, Goger YE, et al. Primary results of transurethral prostate ethanol injection. *Int Urol Nephrol*. 2014 Sep;46(9):1709-13.
8. Bach T, Gilling P, El Hajj A, et al. First Multi-Center All-Comers Study for the Aquablation Procedure. *J Clin Med*. Feb 24 2020; 9(2).
9. Balakrishnan D, Jones P, Somani BK. iTIND: the second-generation temporary implantable nitinol device for minimally invasive treatment of benign prostatic hyperplasia. *Ther Adv Urol*. 2020; 12: 1756287220934355.
10. Bhojani N, Bidair M, Kramolowsky E, et al. Aquablation Therapy in Large Prostates (80-150 mL) for Lower Urinary Tract Symptoms Due to Benign Prostatic Hyperplasia: Final WATER II 5-Year Clinical Trial Results. *J Urol*. Apr 28 2023: 101097JU00000000000003483.
11. Cai HJ, Fang JH, Kong FL, et al. Ultrasound-guided transperineal laser ablation for percutaneous treatment of benign prostatic hyperplasia: A new minimally invasive interventional therapy. *Acta Radiol*. 2022;63(4):553-558
12. Cai H, Zhu C, Fang J. Ultrasound-guided perineal laser ablation versus prostatic arterial embolization for benign prostatic hyperplasia: two similar short-term efficacies. *Acta Radiol*. 2023 May;64(5):2033-2039.
13. Chang Y, Chang J, Wang H. Transurethral balloon dilation of the prostate and transurethral plasmakinetic resection of the prostate in the treatment of prostatic hyperplasia. *Pak J Med Sci*. 2018 May-Jun;34(3): 736-739.
14. Christidis D, Clarebrough E, Hy V, et al. Prostatic artery embolization for benign prostatic obstruction: assessment of safety and efficacy. *World J Urol*. 2018 Apr; 36(4):575-584.
15. Chughtai B, Elterman D, Shore N, et al. The iTind Temporarily Implanted Nitinol Device for the Treatment of Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia: A Multicenter, Randomized, Controlled Trial. *Urology*. Jul 2021; 153: 270-276.
16. Cunningham GR, Kadmon D. Medical treatment of benign prostatic hyperplasia. Up to Date. www.uptodate.com/contents/medical-treatment-of-benign-prostatic-hyperplasia?topicRef=8093&source=see_link.
17. Cunningham GR, Kadmon D. Surgical treatment of benign prostatic hyperplasia. Up to Date. www.uptodate.com/contents/surgical-treatment-of-benign-prostatic-hyperplasia?topicRef=6891&source=see_link.
18. Darson MF, Alexander EE, Schiffman ZJ, et al. Procedural techniques and multicenter postmarket experience using minimally invasive convective radiofrequency thermal therapy with Rezum system for treatment of lower urinary tract symptoms due to benign prostatic hyperplasia. *Res Rep Urol*. 2017 Aug 21;9:159-68.
19. De Nunzio C, Cantiello F, Fiori C, et al. Urinary and sexual function after treatment with temporary implantable nitinol device (iTind) in men with LUTS: 6-month interim results of the MT-06-study. *World J Urol*. Jun 2021; 39(6): 2037-2042.

20. Dixon CM, Cedano ER, Pacik D, et al. Two year results after convective radiofrequency water vapor thermal therapy of symptomatic benign prostatic hyperplasia. *Res Rep Urol*. 2016 Nov 21;8:207-16.
21. ECRI Institute. Optilume Drug-coated Balloon (Urotronic, Inc.) for Treating Urethral Stricture Disease. Plymouth Meeting (PA): ECRI Institute; 2022 March. (Clinical Evidence Assessment).
22. Elliott SP, Coutinho K, Robertson KJ, et al. One-Year Results for the ROBUST III Randomized Controlled Trial Evaluating the Optilume Drug-Coated Balloon for Anterior Urethral Strictures. *J Urol*. Apr 2022; 207(4):866-875.
23. Elterman D, Gao B, Lu S, et al. New Technologies for Treatment of Benign Prostatic Hyperplasia. *Urol Clin North Am*. 2022 Feb;49(1):11-22.
24. Elterman DS, Foller S, Ubrig B, et al. Focal bladder neck cautery associated with low rate of post-Aquablation bleeding. *Can J Urol*. 2021 Apr;28(2):10610-10613.
25. Elterman DS, Coutinho K, Hagedorn JC. How I Do It: The Optilume drug-coated balloon for urethral strictures. *Can J Urol*. 2020 Aug;27(4):10322-10328.
26. Elterman D, Gilling P, Roehrborn C, et al. Meta-analysis with individual data of functional outcomes following Aquablation for lower urinary tract symptoms due to BPH in various prostate anatomies. *BMJ Surg Interv Health Technol*. 2021; 3(1): e000090.
27. Fiori C, De Cillis S, Volpi G, et al. iTIND for BPH: Technique and procedural outcomes: A narrative review of current literature. *Turk J Urol*. Nov 2021; 47(6): 470-481.
28. Food and Drug Administration (2017). Aquabeam System Device Classification Under Section 513(f)(2)(De Novo). www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm?ID=DEN170024.
29. Food and Drug Administration. www.accessdata.fda.gov/cdrh_docs/pdf18/K180237.pdf.
30. Foster HE, Barry MJ, Dahm P, et al. Surgical Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: AUA Guideline. *J Urol*. Sep 2018; 200(3): 612-619.
31. Franco JV, Jung JH, Imamura M, et al. Minimally invasive treatments for lower urinary tract symptoms in men with benign prostatic hyperplasia: a network meta-analysis. *Cochrane Database Syst Rev*. Jul 15 2021; 7(7): CD013656.
32. Gilling PJ, Barber N, Bidair M, et al. Five-year outcomes for Aquablation therapy compared to TURP: results from a double-blind, randomized trial in men with LUTS due to BPH. *Can J Urol*. Feb 2022; 29(1): 10960-10968.
33. Gilling P, Reuther R, Kahokehr A, Fraundorfer M. Aquablation- image-guided robot-assisted waterjet ablation of the prostate: initial clinical experience. *BJU Int*. 2016 Jun;117(6):923-9.
34. Gilling P, Barber N, Bidair M, et al. Three-year outcomes after Aquablation therapy compared to TURP: results from a blinded randomized trial. *Can J Urol*. Feb 2020; 27(1): 10072-10079.
35. Gilling P, Barber N, Bidair M, et al. WATER: A Double-Blind, Randomized, Controlled Trial of Aquablation (R) vs Transurethral Resection of the Prostate in Benign Prostatic Hyperplasia. *J Urol*. May 2018; 199(5): 1252-1261.

36. Gilling PJ, Barber N, Bidair M, et al. Randomized Controlled Trial of Aquablation versus Transurethral Resection of the Prostate in Benign Prostatic Hyperplasia: One-year Outcomes. *Urology*. Mar 2019; 125: 169-173.
37. Grosso M, Balderi A, Arno M, et al. Prostatic artery embolization in benign prostatic hyperplasia: Preliminary results in 13 patients. *Radiol Med*. 2015;120(4):361-368.
38. Hwang EC, Jung JH, Borofsky M et al. Aquablation of the prostate for the treatment of lower urinary tract symptoms in men with benign prostatic hyperplasia. *Cochrane Database Syst Rev*. 2019 Feb;2(2):CD013143.
39. IOM (Institute of Medicine). 2011. *Clinical Practice Guidelines We Can Trust*. Washington, DC: The National Academies Press.
40. Kadner G, Valerio M, Giannakis I, et al. Second generation of temporary implantable nitinol device (iTind) in men with LUTS: 2 year results of the MT-02-study. *World J Urol*. Dec 2020; 38(12): 3235-3244.
41. Kang TW, Jung JH, Hwang EC, et al. Convective radiofrequency water vapour thermal therapy for lower urinary tract symptoms in men with benign prostatic hyperplasia. *Cochrane Database Syst Rev*. Mar 25 2020; 3(3): CD013251.
42. Kaplan SA, Pichardo M, Rijo E, et al. One-year outcomes after treatment with a drug-coated balloon catheter system for lower urinary tract symptoms related to benign prostatic hyperplasia. *Prostate Cancer Prostatic Dis*. December 2021; 24(4):1073-1079
43. Lebdaï S, Delongchamps NB, Sapoval M, et al. Early results and complications of prostatic arterial embolization for benign prostatic hyperplasia. *World J Urol*. 2016;34(5):625-632.
44. Lerner LB, McVary KT, Barry MJ, et al. Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: AUA GUIDELINE PART II- Surgical Evaluation and Treatment. *J Urol*. Oct 2021; 206(4): 818-826.
45. Liu Z, Li YW, Wu WR, Lu Q. Long-term clinical efficacy and safety profile of transurethral resection of prostate versus plasmakinetic resection of the prostate for benign prostatic hyperplasia. *Urology*. 2017 May;103:198-203.
46. Mann RA, Virasoro R, DeLong JM, et al. A drug-coated balloon treatment for urethral stricture disease: Two-year results from the ROBUST I study. *Can Urol Assoc J*. February 2021; 15(2):20-25
47. McVary KT, El-Arabi A, Roehrborn C. Preservation of Sexual Function 5 Years After Water Vapor Thermal Therapy for Benign Prostatic Hyperplasia. *Sex Med*. Dec 2021; 9(6): 100454.
48. McVary KT, Gange SN, Gittelman MC, et al. Minimally Invasive prostate convective water vapor energy ablation: a multicenter, randomized, controlled study for the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia. *J Urol*. May 2016; 195(5): 1529-1538.
49. McVary KT, Gittelman MC, Goldberg KA, et al. Final 5-Year Outcomes of the Multicenter Randomized Sham-Controlled Trial of Rezum Water Vapor Thermal Therapy for Treatment of Moderate-To-Severe Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia. *J Urol*. Sep 2021; 206(3): 715- 724.

50. McVary KT, Roehrborn CG. Three year outcomes of the prospective, randomized controlled Rezum system study: convective radiofrequency thermal therapy for treatment of lower urinary tract symptoms due to benign prostatic hyperplasia. *Urology*. Jan 2018; 111: 1-9.
51. McVary KT, Rogers T, Roehrborn CG. Rezum water vapor thermal therapy for lower urinary tract symptoms associated with benign prostatic hyperplasia: 4-year results from randomized controlled study. *Urology*. Apr 2019; 126: 171-179.
52. Misrai V, Rijo E, Zorn KC, et al. Waterjet Ablation Therapy for Treating Benign Prostatic Obstruction in Patients with Small- to Medium-size Glands: 12- month Results of the First French Aquablation Clinical Registry. *Eur Urol*. Nov 2019; 76(5): 667-675.
53. Mollengarden D, Goldberg K, Wong D, et al. Convective radiofrequency water vapor thermal therapy for benign prostatic hyperplasia: a single office experience. *Prostate Cancer Prostatic Dis*. 2018 Sep;21(3):379-385.
54. National Institute for Health and Care Excellence (NICE). Aquablation robotic therapy for lower urinary tract symptoms caused by benign prostatic hyperplasia. January 1, 2023. www.nice.org.uk/advice/mib315/chapter/Clinical-and-technical-evidence.
55. National Institute for Health and Care Excellence (2020). Rezum for treating lower urinary tract symptoms secondary to benign prostatic hyperplasia. www.nice.org.uk/guidance/mtg49/chapter/1-Recommendations.
56. National Institute for Health and Care Excellence (NICE). Interventional procedures guidance: prostatic urethral temporary implant insertion for lower urinary tract symptoms caused by benign prostatic hyperplasia [IPG737]. September 21, 2022; www.nice.org.uk/guidance/ipg737.
57. National Institute for Health and Care Excellence (2023). Transurethral water jet ablation for lower urinary tract symptoms caused by benign prostatic hyperplasia. [IPG770]. www.nice.org.uk/guidance/ipg770.
58. NICE -- Optilume for anterior urethral strictures. National Institute for Health and Care Excellence. Medtech innovation briefing (January 2021) (MIB241). Available at: www.nice.org.uk
59. Optilume® Drug Coated Balloon. Manufacturer Information. Available at: www.urotronic.com
60. Porpiglia F, Fiori C, Bertolo R. 3 year follow-up of temporary implantable nitinol device implantation for the treatment of benign prostatic obstruction. *BJU Int*. 2018 Jul;122(1):106-112.
61. Porpiglia F, Fiori C, Amparore D, et al. Second-generation of temporary implantable nitinol device for the relief of lower urinary tract symptoms due to benign prostatic hyperplasia: results of a prospective, multicentre study at 1 year of follow-up. *BJU Int*. Jun 2019; 123(6): 1061-1069.
62. Porpiglia F, Fiori C, Bertolo R, et al. Temporary implantable nitinol device (TIND): a novel, minimally invasive treatment for relief of lower urinary tract symptoms (LUTS) related to benign prostatic hyperplasia (BPH): feasibility, safety and functional results at 1 year of follow-up. *BJU Int*. Aug 2015; 116(2): 278-87.

63. Porto JG, Titus R, Camargo F, Bhatia A, Ahie N, Blachman-Braun R, Malpani A, Lopategui DM, Herrmann TRW, Marcovich R, Shah HN. Minimally invasive techniques in quest of Holy Grail of surgical management of enlarged prostates: a narrative review. *World J Urol.* 2024 Jan 13;42(1):35.
64. Roehrborn CG, Wilson TH, Black LK. Quantifying the contribution of symptom improvement to satisfaction of men with moderate to severe benign prostatic hyperplasia: 4-year data from the CombAT trial. *J Urol.* May 2012; 187(5): 1732-8.
65. Sandhu JS, Bixler BR, Dahm P, et al. Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia (BPH): AUA Guideline Amendment 2023. *J Urol.* Jan 2024; 211(1): 11-19.
66. Sarma AV, Wei JT. Clinical practice. Benign prostatic hyperplasia and lower urinary tract symptoms. *N Engl J Med.* Jul 19 2012; 367(3): 248-57.
67. SP Elliott, K Coutinho, KJ Robertson, et al. One-Year Results for the ROBUST III Randomized Controlled Trial Evaluating the Optilume® Drug-Coated Balloon for Anterior Urethral Strictures. *J Urol.* 2022;207(4):866-75.
68. Sun F, Sun X, Shi Q, Zhai Y. Transurethral procedures in the treatment of benign prostatic hyperplasia: A systematic review and meta-analysis of effectiveness and complications. *Medicine (Baltimore).* 2018 Dec;97(51)e13360.
69. Tanneru K, Jazayeri SB, Alam MU, et al. An Indirect Comparison of Newer Minimally Invasive Treatments for Benign Prostatic Hyperplasia: A Network Meta-Analysis Model. *J Endourol.* 2021 Apr;35(4):409-416. doi: 10.1089/end.2020.0739. Epub 2021 Jan 25.
70. Teoh JY, Chiu PK, Yee CH, et al. Prostatic artery embolization in treating benign prostatic hyperplasia: A systematic review. *Int Urol Nephrol.* 2017;49(2):197-203.
71. Thurmond P, Bose S, Lerner LB. Holmium laser for the surgical treatment of benign prostatic hyperplasia. *Can J Urol.* 2016;23(4):8356-62.
72. UpToDate. Medical treatment of benign prostatic hyperplasia. 2024. Available at: www.uptodate.com/contents/medical-treatment-of-benign-prostatic-hyperplasia?search=benign%20prostatic%20hyperplasia&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1.
73. U.S. Food and Drug Administration (FDA) Summary of Safety and Effectiveness Data. Optilume Urethral Drug Coated Balloon. June 30, 2023. Available www.accessdata.fda.gov/cdrh_docs/pdf21/P210020B.pdf.
74. U. S. Food and Drug Administration. Optilume® Urethral Drug Coated Balloon (P210020) December 3, 2021. Available at: www.accessdata.fda.gov
75. VanDyke ME, Morey AF, Coutinho K, Robertson KJ, D'Anna R, Chevli K, et al. Optilume drug-coated balloon for anterior urethral stricture: 2-year results of the ROBUST III trial. *BJUI Compass.* 2024;5(3):366–73.
76. van Kollenburg RAA, van Riel LAMJG, de Bruin DM, et al. Novel minimally invasive treatments for lower urinary tract symptoms: a systematic review and network meta-analysis. *Int Braz J Urol.* 2023 Jul-Aug;49(4):411-427.

77. Virasoro R, DeLong JM, Estrella R, et al. A Drug-Coated Balloon Treatment for Urethral Stricture Disease: Three-Year Results from the ROBUST I Study. *Res Rep Urol*. May 6 2022; 14:177-183.
78. Wessells H, Morey A, Souter L, Rahimi L, Vanni A. Urethral Stricture Disease Guideline Amendment (2023). *J Urol*. 2023 Jul;210(1):64-71.
79. Westwood, J, Geraghty, R, Jones, P, BB et al. Rezum: a new transurethral water vapour therapy for benign prostatic hyperplasia.. *Ther Adv Urol*, Nov 2018;10(11): 327-333.
80. Yamada Y, Furusawa J, Sugimura Y, Kuromatsu. Photoselective vaporization of the prostate: Long-term outcomes and safety during 10 years of follow-up. *J Endourol*. 2016 Dec;30(12): 1306-1311.
81. Zhao C, Yang H, Chen Z, Ye Z. Thulium laser resection versus plasmakinetic resection of prostates in the treatment of benign prostate hyperplasia: A meta-analysis. *J Laparoendosc Adv Surg Tech A*. 2016 Oct; 26(10): 789-798.

POLICY HISTORY:

Medical Policy Group, September 2019

Medical Policy Administration Committee, September 2019

Medical Policy Panel, June 2020

Medical Policy Group, June 2020

Adopted for Blue Advantage, April 2021

Medical Policy Group, July 2021

Medical Policy Group, June 2022

Medical Policy Group, December 2022

Medical Policy Group, June 2023

UM Committee, December 2023: Policy approved by UM Committee for use for Blue Advantage business.

Medical Policy Group, February 2024: Policy updated to allow coverage for prostate artery embolization. Effective March 1, 2024. On draft March 1, 2024, through April 3, 2024.

UM Committee, February 2024: Policy update approved by UM Committee

Medical Policy Group, July 2024: Policy updated to allow coverage for iTind and Optilume effective August 15, 2024. Policy on draft from July 12, 2024, to August 14, 2024.

UM Committee, July 2024: Annual review of policy approved by UM Committee for use for Blue Advantage business.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.