BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Treatment of Benign Prostatic Hyperplasia

Policy #: 725
Latest Review Date: January 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 March 1, 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:

- Holmium laser procedures of the prostate (HoLAP, HoLEP, HoLRP)
- Laser Transurethral Enucleation of the Prostate (TUEP)
- Laser Transurethral Vaporization of the Prostate (TUVP)
- 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)
- Laser Transurethral Enucleation of the Prostate (TUEP)
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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.

For information regarding UroLift, please refer to medical policy #610: Prostatic Urethral Lift.

KEY POINTS:

This evidence review has been updated regularly with the search of the PubMed database. Most recently, the literature was reviewed through November 17, 2023.

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 outcomes.

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 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 the 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 symptom 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.

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) and included the following recommendations 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 ml. (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 the prostate volume is 30 to 80 ml. (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. 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 2018, NICE issued the following guidance on transurethral water jet ablation for LUTS caused by BPH:

"The evidence on transurethral water jet ablation for lower urinary tract symptoms caused by benign prostatic hyperplasia raises no major safety concerns. The evidence on efficacy is limited in quantity. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research."

The guidance also states, "NICE encourages further research into transurethral water jet ablation for LUTS caused by BPH and may update the guidance on publication of further evidence. Further research should report long-term follow-up and include reintervention rates."

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 as of March 7, 2023

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, TUVP, 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

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 ≥ 30cm3 and ≤ 80cm3. The Rezūm System is also indicated for the treatment of prostate with hyperplasia of the central zone and/or a median lobe.

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.

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)
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 postoperative bleeding, including ultrasound guidance, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included when performed)

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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, January 2024
Medical Policy Group, February 2024: Policy updated to allow coverage for prostate artery embolization. Effective March 1, 2024.
UM Committee, February 2024: Annual review of policy approved by UM Committee for use for Blue Advantage business.
