BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Treatment of Benign Prostatic Hyperplasia

Policy #: 725
Category: Medical

Latest Review Date: July 2021
Policy Grade: B

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:

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)
- 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

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 is the most commonly presenting urological complaint and can have a significant impact on the 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 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.

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

KEY POINTS:

This evidence review has been updated regularly with search of the MEDLINE database. Most recently, the literature was reviewed through May 13, 2021.

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 have shown results similar to TURP. The evidence is sufficient to determine the effects of these techniques on net health outcome.

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 hyperplasia and lower urinary tract symptoms who receive aquablation, the evidence includes one noninferiority RCT of aquablation compared to TURP in 187 patients with 3 years of follow-up. The outcomes of interest are symptoms, 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 end point 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 3 years, improvements remained similar between groups. 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.

Practice Guidelines and Position Statements

American Urological Association

The American Urological Association (2018, amended 2019, 2020) issued clinical practice guidelines on benign prostatic hyperplasia (amended 2019) and made the following relevant recommendations:

- Water vapor thermal therapy may be offered to patients with lower urinary tract symptoms attributed to benign prostatic hyperplasia provided prostate volume <80 g (Moderate Recommendation; Evidence Level: Grade C)

- Water vapor thermal therapy may be offered to eligible patients who desire preservation of erectile and ejaculatory function. (Conditional Recommendation; Evidence Level: Grade C)
- Aquablation may be offered to patients with LUTS attributed to BPH provided prostate volume >30/<80g. (Conditional Recommendation; Evidence Level: Grade C).
- Clinicians should inform patients of the possibility of treatment failure and the need for additional or secondary treatments when considering surgical and minimally-invasive treatments for LUTS secondary to BPH. (Clinical Principle).

National Institute for Health and Care Excellence
In 2020, the National Institute for Health and Care Excellence (NICE) issued the following guidance on Rezum for treatment of LUTS secondary to BPH:14,

"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."

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

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 approve 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 treatment of prostate with hyperplasia of the central zone and/or a median lobe.

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 roadmapping, 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 post-operative 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

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.