BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Treatment of Benign Prostatic Hyperplasia

Policy #: 725
Category: Medical

Latest Review Date: June 2020
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, or BPH, develops from excessive cell proliferation in the prostate. An enlarged prostate gland has been proposed to contribute to the overall lower urinary tract symptoms (LUTS) complex via at least two routes: (1) direct bladder outlet obstruction from enlarged tissue and (2) from increased smooth muscle tone and resistance within the enlarged gland. The associated chronic bladder-outlet obstruction often leads to signs and symptoms. The frequent symptoms of BPH include: urinary retention, urinary frequency, incomplete bladder emptying, gross hematuria (visible blood in the urine), and renal insufficiency.
Treatment for BPH includes watchful waiting, medical management, standard surgical treatments, or minimally invasive treatments. For men who have symptoms but do not have discomfort or exhibit complications from BPH, watchful waiting may be utilized. Medical management may be indicated for individuals with mild to moderate symptoms or for men who are unwilling to undergo surgery or are poor surgical candidates. Surgical management may be indicated for men who do not respond to medications, develop upper urinary tract injuries (e.g. hydronephrosis) or develop lower urinary tract injuries (e.g. recurrent urinary tract infections). Untreated BPH may worsen over time and increase the risk of stones, infection, or kidney failure.

The goal of treatment for BPH has been to improve symptoms, such as urinary retention or hesitancy, that result from prostatic enlargement. More recently, treatment has been focused on altering disease progression and preventing complications associated with BPH. Standard surgical treatments such as transurethral resection of the prostate (TURP), transurethral incision of the prostate (TUIP), and open prostatectomy may be accompanied by complications such as blood loss, and side effects such as incontinence and retrograde ejaculation. Newer surgical techniques that use lasers, as well as minimally invasive techniques that use various sources of energy such as heat, microwaves, radiofrequency, and ultrasound, have been developed.
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 14, 2020.

Summary

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.

Practice Guidelines and Position Statements
American Urological Association

The AUA published a Clinical Guideline in 2018 for the surgical management of LUTS attributed to BPH.

TURP should be offered as a treatment option for men with LUTS attributed to BPH.	(Moderate Recommendation; Evidence Level: Grade B)
Clinicians may use a monopolar or bipolar approach to TURP, depending on their expertise with these techniques.	(Expert Opinion)
Clinicians should consider open, laparoscopic or robotic assisted prostatectomy, depending on their expertise with these techniques, for patients with large prostates.	(Moderate Recommendation; Evidence Level: Grade C)
TUIP should be offered as an option for patients with prostates ≤30g for the surgical treatment of LUTS attributed to BPH.	(Moderate Recommendation; Evidence Level: Grade B)
Bipolar TUVP may be offered to patients for the treatment of LUTS attributed to BPH.	(Conditional Recommendation; Evidence Level: Grade B)
Clinicians should consider PVP as an option using 120W or 180W platforms for patients for the treatment of LUTS attributed to BPH.	(Moderate Recommendation; Evidence Level: Grade B)

TUMT may be offered to patients with LUTS attributed to BPH; however, patients should be informed that surgical retreatment rates are higher compared to TURP.	(Conditional Recommendation; Evidence Level: Grade C)
Water vapor thermal therapy may be offered to patients with LUTS attributed to BPH provided prostate volume <80g; however, patients should counseled regarding efficacy and retreatment rates.	(Conditional 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)
TUNA is not recommended for the treatment of LUTS attributed to BPH.	(Expert Opinion)
Clinicians should consider holmium laser enucleation of the prostate (HoLEP) or thulium laser enucleation of the prostate (ThuLEP), depending on their expertise with either technique, as prostate size-independent suitable options for the treatment of LUTS attributed to BPH.	(Moderate Recommendation; Evidence Level: Grade B)
Aquablation may be offered to patients with LUTS attributed to BPH provided prostate volume >30/<80g; however, patients should be informed that long term evidence of efficacy and retreatment rates remain limited.	(Conditional Recommendation; Grade C)
PAE is not recommended for the treatment of LUTS attributed to BPH outside the context of a clinical trial.	(Expert Opinion)
HoLEP, PVP, and ThuLEP should be considered in patients who are at higher risk of bleeding, such as those on anti-coagulation drugs.	(Expert Opinion)

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

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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
