

## Corporate Medical Policy

# Transurethral Water Vapor Thermal Therapy for Benign Prostatic Hyperplasia

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**Last CAP Review:** N/A  
**Next CAP Review:** 11/2020  
**Last Review:** 4/2020

### Description of Procedure or Service

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Benign prostatic hyperplasia (BPH) is a common condition in older men, affecting up to 40% of men in their 50s, 70% of those between ages 60 and 69, and almost 80% of those ages 70 and older. 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 can lead to lower urinary tract symptoms to include urinary frequency, urgency, irregular flow, weak stream, straining, and nocturia. Lower urinary tract symptoms is the most commonly presenting urological complaint and can have a significant impact on the quality of life.

The decision whether to treat BPH is based on the impact of symptoms on quality of life and the potential side effects of treatment. Options for medical treatment of lower urinary tract symptoms include alpha-1-adrenergic antagonists, 5-alpha-reductase inhibitors, antimuscarinic agents, beta agonists, and phosphodiesterase-5 inhibitors. Medications may be used as monotherapy or in combination but may be associated with significant side effects.

Patients with persistent symptoms despite medical treatment, or patients experiencing significant side effects with medical therapy, or patients who are unable to tolerate medical alternatives may consider procedural intervention. Transurethral resection of the prostate (TURP) is generally considered the reference standard for comparisons of other BPH treatments. In the perioperative period, TURP is associated with risks of any operative procedure (e.g., anesthesia risks, blood loss). Although short-term mortality risks are generally low, one large prospective study with 10,654 patients reported the following short-term complications: failure to void (5.8%), surgical revision (5.6%), significant urinary tract infection (3.6%), bleeding requiring transfusions (2.9%), and transurethral resection syndrome (1.4%). TURP is associated with risk of erectile dysfunction (~10%) and urinary incontinence (~2%).

Several alternatives to TURP, including minimally invasive procedures have been developed. Clinical outcomes using these alternative therapies are generally compared individually to TURP. However, most comparisons with TURP are indirect, with head to head comparisons lacking in the published literature.

Transurethral water vapor thermal therapy has been investigated as a minimally invasive alternative to TURP. The procedure uses radiofrequency-generated water vapor (~103°C) thermal energy to ablate prostate tissue through convective transfer of energy. A proposed advantage over conductive heat transfer (e.g., transurethral microwave thermotherapy [TUMT], transurethral needle ablation [TUNA]) includes limiting thermal effects to the targeted treatment zone.

The Rezūm™ system is a form of transurethral water vapor thermal therapy and consists of a radiofrequency generator and a single-use transurethral delivery device which incorporates a

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standard cystoscopy lens. The procedure is generally performed in an outpatient/in-office setting without the need for general anesthesia.

The Rezūm system is not restricted by prostate morphology and is used to treat all prostate zones (i.e., not restricted to use in the setting of no median lobe obstruction).

## Regulatory Status

In September 2016, the Rezum System™ (Boston Scientific) was cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process (K150786). The Food and Drug Administration determined that this device was substantially equivalent to existing devices (Medtronic Prostiva devices). Rezum™ is intended to relieve symptoms, obstructions, and reduce prostate tissue associated with benign prostatic hyperplasia. It is indicated for men  $\geq 50$  years of age with a prostate volume  $\geq 30\text{cm}^3$  and  $\leq 80\text{cm}^3$ . The Rezum System™ is also indicated for the treatment of prostate with hyperplasia of the central zone and/or a median lobe.

## Related Policies

Prostatic Urethral Lift

**\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

## Policy

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**BCBSNC will provide coverage for transurethral water vapor thermal therapy (Rezūm) for benign prostatic hyperplasia when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.**

## Benefits Application

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This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore, member benefit language should be reviewed before applying the terms of this medical policy.

## When Transurethral Water Vapor Thermal Therapy for Benign Prostatic Hyperplasia is covered

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Transurethral water vapor thermal therapy (Rezūm system) may be considered **medically necessary** for the treatment of moderate to severe lower urinary obstruction due to benign prostatic hyperplasia (BPH) when ALL the following criteria are met:

1. Patient is not an appropriate candidate for an invasive surgical procedure using general anesthesia, such as transurethral resection of the prostate, or the patient opts to undergo a minimally invasive procedure.
2. Patient has persistent or progressive lower urinary tract symptoms or is unable to tolerate medical therapy for BPH, after an appropriate trial period, defined as one month following an alpha-1-adrenergic antagonist or 3 months following a 5-alpha-reductase inhibitor, or intolerance or other contraindication to medical therapy.
3. Prostate gland volume is estimated to be  $\geq 30$  to  $\leq 80$  cc, by ultrasound or other radiologic assessment.
4. The patient is 50 years of age or older.
5. The Rezūm device system is used by a physician trained in the specialty of Urology and trained in use of the Rezūm system.

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## When Transurethral Water Vapor Thermal Therapy for Benign Prostatic Hyperplasia is not covered

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Transurethral water vapor thermal therapy is considered **investigational** as a treatment of benign prostatic hyperplasia when the above criteria are not met.

Repeat use of transurethral water vapor thermal therapy as a treatment of BPH is considered investigational.

Use of transurethral water vapor therapy as a treatment of BPH after use of other minimally invasive procedures for BPH (e.g., prostatic urethral lift) is considered investigational.

Use of transurethral water vapor therapy as a treatment of BPH in a patient with a diagnosis of prostate cancer is considered investigational.

## Policy Guidelines

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Evidence summary:

For individuals who have benign prostatic hyperplasia who receive transurethral water vapor thermal therapy, the evidence includes one small, sham-controlled randomized trial with a four-year uncontrolled follow-up phase (McVary, 2018). The outcomes of interest are symptoms, quality of life, and treatment-related morbidity. At three months, lower urinary tract symptoms 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 four years of follow-up. The evidence is limited by the small sample size, short-term duration, lack of blinding of longer-term outcomes, and lack of direct comparison to alternative treatments such as transurethral resection of the prostate. However, four-year outcome reports show efficacy and retreatment rates at least as comparable to Urolift, and a cost-effectiveness analysis suggests that Rezūm may represent a less costly alternative to Urolift. The evidence is sufficient to determine the effects of the technology on health outcomes.

A sham-controlled, double-blind, randomized study reported three-year outcomes in 197 men with moderate to severe symptomatic BPH, randomized 2:1 to treatment with Rezūm or control procedure with rigid cystoscopy. (McVary, 2017, 2018) The study included men who were 50 years of age or greater, with International Prostate Symptom Score (IPSS)  $\geq 13$ , maximum flow rate  $\leq 15$  mL/s and prostate volume 30 to 80 cc. Treatment with Rezūm resulted in IPSS improvement at 3 months of 50% compared with 20% for controls, ( $p < .0001$ ). Symptom relief of at least 50% improvement in IPSS, quality of life and maximum flow rate remained durable throughout three years ( $p < .0001$ ). Men with a treated median lobe had similar responses. Outcomes were consistently durable for over 4 years, with surgical retreatment rate 4.4% over 4 years.

A cost-effectiveness analysis of six therapies for the treatment of BPH included a comparison of combination prescription drug therapy, minimally invasive therapies to include Rezūm and Urolift, and invasive surgical procedures including TURP. (Ulchaker, 2017) The costs and cost-effectiveness were analyzed over 2 years. The minimally invasive therapies resulted in similar degrees of relief of lower urinary tract symptoms at year 2, however, the cost of Urolift (based on 4 implants) was more than twice as much as Rezūm.

Practice Guidelines and Position Statements:

The American Urologic Association (AUA) BPH Clinical Guideline states that “Water vapor thermal therapy may be offered to patients with LUTS attributed to BPH provided prostate

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volume is <80 g; however, patients should be counseled regarding efficacy and retreatment rates". (Conditional Recommendation; Evidence Level: Grade C)

No studies of repeat treatments using transurethral water vapor thermal therapy as a treatment of benign prostatic hyperplasia were identified in the clinical literature. The evidence is insufficient to determine that the technology results in a meaningful improvement in the net health outcome.

## Billing/Coding/Physician Documentation Information

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable service codes: 53854*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

## Scientific Background and Reference Sources

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McVary KT, Rogers T, Roehrborn CG. Rezūm Water Vapor Thermal Therapy for Lower Urinary Tract Symptoms Associated With Benign Prostatic Hyperplasia: 4-Year Results From Randomized Controlled Study. *Urology*. 2019 Apr;126:171-179.

McVary KT, Roehrborn CG. Three-Year Outcomes of the Prospective, Randomized Controlled Rezūm System Study: Convective Radiofrequency Thermal Therapy for Treatment of Lower Urinary Tract Symptoms Due to Benign Prostatic Hyperplasia. *Urology*. 2018 Jan;111:1-9.

Reich O, Gratzke C, Bachmann A, et al. Morbidity, mortality and early outcome of transurethral resection of the prostate: a prospective multicenter evaluation of 10,654 patients. *J Urol*. Jul 2008;180(1):246-249.

Ulchaker JC, Martinson MS. Cost-effectiveness analysis of six therapies for the treatment of lower urinary tract symptoms due to benign prostatic hyperplasia. *Clinicoecon Outcomes Res*. 2017 Dec 29;10:29-43.

Westwood, JJ, Geraghty, RR, Jones, PP, Rai, BB, Somani, BB. Rezum: a new transurethral water vapour therapy for benign prostatic hyperplasia. *Ther Adv Urol*, 2018 Oct 23;10(11). PMID 30344644

American Urological Association Benign Prostatic Hyperplasia: Surgical Management of Benign Prostatic Hyperplasia/Lower Urinary Tract Symptoms, 2018 (amended 2019) Available at: [https://www.auanet.org/guidelines/benign-prostatic-hyperplasia-\(bph\)-guideline](https://www.auanet.org/guidelines/benign-prostatic-hyperplasia-(bph)-guideline).

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.49, 6/13/2019

Medical Director review 4/2020

# Transurethral Water Vapor Thermal Therapy for Benign Prostatic Hyperplasia

## Policy Implementation/Update Information

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| 11/12/19 | New policy developed. Transurethral water vapor thermal therapy (Rezūm) for BPH may be considered medically necessary with criteria. (hb)   |
| 4/14/20  | Medical Director review. Description section updated. When Covered section updated. Added three additional non covered indications to When Not Covered section. Updated Policy Guidelines. Policy noticed 4/14/2020 for policy effective date 6/23/2020. (sk) |

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.