

## Medical Coverage Policy | Transurethral Water Vapor Thermal Therapy for Benign Prostatic Hyperplasia



**EFFECTIVE DATE:** 07|01|2021

**POLICY LAST UPDATED:** 06|16|2021

### OVERVIEW

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. 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 including urinary frequency, urgency, irregular flow, weak stream, straining, and waking up at night to urinate. Lower urinary tract symptoms (LUTS) is the most commonly presenting urological complaint and can have a significant impact on the quality of life.

### MEDICAL CRITERIA

#### Medicare Advantage Plans

Blue Cross and Blue Shield of Rhode Island (BCBSRI) follows the medical necessity criteria from Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations (NCD/LCD). Please use the online tool for participating providers. See the Related Policies section.

### PRIOR AUTHORIZATION

#### Medicare Advantage Plans

Prior Authorization is required for Medicare Advantage Plans only. Please use the online tool for participating providers. See the Related Policies section.

#### Commercial Products

Not applicable.

### POLICY STATEMENT

#### Commercial Products

Transurethral water vapor thermal therapy is considered not medically necessary as a treatment of benign prostatic hyperplasia as the evidence is insufficient to determine the effects of the technology on health outcomes.

### COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/coverage or surgery benefit.

### BACKGROUND

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.

Transurethral water vapor thermal therapy has been investigated as a minimally invasive alternative to transurethral resection of the prostate. The procedure uses radiofrequency-generated water vapor (~103°C) thermal energy to ablate prostate tissue.

For individuals who have benign prostatic hyperplasia who receive transurethral water vapor thermal therapy, the evidence includes one small, short-term sham-controlled randomized controlled trial with a four-year uncontrolled follow-up phase. 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 comparison to alternative treatments such as transurethral resection of the prostate. The evidence is insufficient to determine the effects of the technology on health outcomes.

## REGULATORY STATUS

In September 2016, the Rezum System™ (NxThera, Inc) 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.

## CODING

### Commercial Products

The following code(s) is not medically necessary:

53854 Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy)

## RELATED POLICIES

Prior Authorization via Web-Based Tool for Procedures

## PUBLISHED

Provider Update, August 2021

Provider Update, July 2020

Provider Update, November 2019

## REFERENCES

- 1.UpToDate. Medical treatment of benign prostatic hyperplasia. 2019. Available at: [https://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](https://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). Accessed May 28, 2019.
2. 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
3. McVary, KK, Roehrborn, CC. 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*, 2017 Nov 11;111:1-9. PMID 29122620
4. McVary, KK, Gange, SS, Gittelman, MM, Goldberg, KK, Patel, KK, Shore, NN, Levin, RR, Rousseau, MM, Beahrs, JJ, Kaminetsky, JJ, Cowan, BB, Cantrill, CC, Mynderse, LL, Ulchaker, JJ, Larson, TT, Dixon, CC, Roehrborn, CC. 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.*, 2015 Nov 29;195(5). PMID 26614889

5. McVary, KK, Rogers, TT, Roehrborn, CC. Rezum Water Vapor Thermal Therapy for Lower Urinary Tract Symptoms Associated With Benign Prostatic Hyperplasia: 4-Year Results From Randomized Controlled Study. *Urology*, 2019 Jan 25;126:171-179. PMID 30677455
6. 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). Accessed May 28, 2019.

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