

(20149)

Medical Benefit		Effective Date: 12/01/19	Next Review Date: 09/20
Preauthorization	Yes	Review Dates: 09/19	

Preauthorization is required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> • With benign prostatic hyperplasia and lower urinary tract symptoms 	Interventions of interest are: <ul style="list-style-type: none"> • Transurethral water vapor thermal therapy 	Comparators of interest are: <ul style="list-style-type: none"> • Conservative approaches • Medical therapy • Transurethral resection of the prostate • Other minimally invasive procedure 	Relevant outcomes include: <ul style="list-style-type: none"> • Symptoms • Functional Outcomes • Quality of life • Procedure-related morbidity

DESCRIPTION

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. 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.

SUMMARY OF EVIDENCE

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.

POLICY

Transurethral water vapor thermal therapy is considered **investigational** as a treatment of benign prostatic hyperplasia.

MEDICARE ADVANTAGE

One water vapor thermal therapy treatment for lower urinary tract symptoms attributable to benign prostatic hyperplasia (LUTS/BPH) treatment may be considered **medically necessary** once in patients who meet all of the following criteria:

1. Age \geq 50
2. Symptomatic despite maximal medical management including ALL of the following:
 - International Prostate Symptom Score (IPSS) \geq 13
 - Maximum urinary flow rate (Qmax) of \leq 15 mL/s (voided volume greater than 125 cc)
 - Failure, contraindication or intolerance to at least three months of conventional medical therapy for BPH (e.g., alpha blocker, PDE5 Inhibitor, finasteride/dutasteride)
3. Prostate volume of 30-80 cc
4. Obstructing median lobe
5. Poor candidate for other surgical interventions for BPH due to underlying disease (e.g., cardiac disease, pulmonary disease, etc.), or at high risk of bleeding
6. The patient must have no contraindications which include all of the following:
 - Known or suspected prostate cancer (based on NCCN Prostate Cancer Early Detection guidelines) or a prostate specific antigen (PSA) $>$ 10 ng/mL
 - Active urinary tract infection
 - History of bacterial prostatitis in the past three months
 - Urinary retention (e.g., PVR $>$ 250-300 mL, catheterization requirement, history of being unable to void)
 - Prior prostate surgery
 - Neurogenic bladder
 - Active urethral stricture (i.e., the source of the current LUTS)

BACKGROUND

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 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 the quality of life.¹

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.²

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.³

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 greater than 50 years of age with a prostate volume greater than 30cm³ and less than 80cm³. The Rezum System™ is also indicated for the treatment of prostate with hyperplasia of the central zone and/or a median lobe.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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. 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, Behrs, 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.
7. National Government Services, Inc. (Primary Geographic Jurisdiction 06 & K - Illinois, Minnesota, Wisconsin, Connecticut, New York - Entire State, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont) Local Coverage Determination (LCD): Water Vapor Thermal Therapy for LUTS/BPH (L37808), Revision Effective Date for services performed on or after 01/01/2019.