

**VHA Office of Integrated Veteran Care**  
**Clinical Determination and Indication**  
**Transurethral Water Vapor Thermal Therapy for Lower Urinary Tract Symptoms**  
**and Benign Prostatic Hyperplasia**

**CDI Number: 00034**

**Original Effective Date: October 1, 2024**

**Last Review Date: October 1, 2024**

**I. Disclaimer**

This document is currently in draft and is intended to be used as a reference for non-VA providers and not intended to replace clinical judgement when determining care pathways. These guidelines do not guarantee benefits or constitute medical advice.

**II. Clinical Determinations and Indications**

**a. Indications for Transurethral Water Vapor Thermal Therapy for Lower Urinary Tract Symptoms/Benign Prostatic Hyperplasia**

Transurethral water vapor thermal therapy is indicated for the treatment of lower urinary tract symptoms (LUTS) and benign prostatic hyperplasia (BPH) and will be considered **medically necessary** when **ALL** the following criteria are met:

- (Age greater than or equal to 40)
- Persistent moderate to severe symptoms despite maximal medical management including **ANY** of the following:
  - International Prostate Symptom Score (IPSS) greater than or equal to 13
  - Maximum urinary flow rate of less than or equal to 15 mL/s (voided volume greater than 125 cc)
  - Failure, contraindication, intolerance, or patient refusal of at least three months of conventional medical therapy for LUTS with BPH (e.g., alpha-blocker, PDE5 Inhibitor, finasteride/dutasteride)
- Prostate enlargement determined by ultrasound or cystoscopy
- Poor candidate for other surgical interventions for BPH

**Note:** Provider should use clinical judgment if prostate volume is greater than 80cc

## b. Limitations/Exclusions

Transurethral water vapor thermal therapy is **not indicated** if any of the following are applicable:

- Active urinary tract infection
- History of bacterial prostatitis in the past three months
- Neurogenic bladder (areflexic/atonic bladder)

Conditions/indications for which transurethral water vapor thermal therapy is **not medically necessary** include, but are not limited to, the following:

- Prostate cancer

For all indications not listed in section II.a. of this document, transurethral water vapor thermal therapy is considered **not medically necessary** due to insufficient evidence of efficacy and safety.

## c. Description of Treatment

Transurethral water vapor thermal therapy is a minimally invasive procedure used to treat LUTS secondary to BPH. This procedure can be done in a urologist's office, outpatient surgery center, or hospital based operating room under light sedation and local anesthesia.

During the procedure, a urologist uses a hand-held device to pass a transurethral needle through the urethra to reach the prostate. The system delivers an injection of steam directly into the swollen prostate tissue. As the steam condenses, heat is released, leading the cells to breakdown and die. Over time, the body absorbs the treated tissue as part of the natural healing process.

Following the procedure, patients are typically sent home with an indwelling Foley catheter for 3 to 7 days. Relief from LUTS is typically experienced within one month of the procedure.

## III. Background and Supporting Information

The following information is for reference purposes only in accordance with the medical benefits package outlined in 38 C.F.R. § 17.38 (b). Each subsection supports VA's determinations for medical necessity and alignment with generally accepted standards of medical practice.

### a. Background of Water Vapor Thermal Therapy for Lower Urinary Tract Symptoms/Benign Prostatic Hyperplasia

The prostate is a small muscular gland within the male reproductive system that gradually enlarges as a person ages, leading to a condition known as benign

prostatic hyperplasia. Benign prostatic hyperplasia (BPH) is common among individuals with prostates over 45 years of age. As the prostate becomes enlarged, it may squeeze the urethra and cause lower urinary tract symptoms (LUTS) such as increased urinary frequency, urgency, irregular flow, weak stream, straining, and nocturia. As these symptoms worsen, they can have a significant negative impact on a person's quality of life.

### **Medical Management**

Early diagnosis of BPH is important, as untreated BPH may lead to other medical conditions such as urinary tract infections, bladder or kidney damage, bladder stones, and incontinence.

The decision to treat BPH depends on the severity of symptoms and the potential side effects of treatment. Treatment options may include medications that relax the muscles of the prostate and bladder neck, and/or block the production of hormones that cause prostate growth. In cases where symptoms persist despite medical management or when significant side effects occur, surgical interventions may be considered.

### **Transurethral Water Vapor Thermal Therapy (Rezūm)**

Transurethral water vapor thermal therapy is a minimally invasive alternative to the traditional surgical procedure, transurethral resection of the prostate (TURP) for BPH. The Rezūm system, approved by the FDA, offers flexibility in treating all prostate zones regardless of prostate shape.

### **Advantages of Transurethral Water Vapor Thermal Therapy (Rezūm)**

- May be done under local anesthesia
- Allows for treatment of enlarged prostate tissue
- Associated with minimal adverse events
- Has minimal sexual side effects such as retrograde ejaculation or erectile dysfunction
- Has consistent outcomes in relieving LUTS, improving urinary flow, and improving quality of life

### **Disadvantages of Transurethral Water Vapor Thermal Therapy (Rezūm)**

- May require longer catheterization time as the patient will be discharged with an indwelling Foley catheter for 3 to 7 days
- May result in an increased duration of dysuria, sensation of pain, or burning associated with urination
- Not all people are candidates for this procedure

## b. Research, Clinical Trials, and Evidence Summaries

Clinical research shows that the water vapor thermal therapy is a safe and effective procedure to relieve LUTS due to BPH and the treatment appears effective for at least five years.

McVary et al. (2021) conducted a multicenter randomized sham-controlled trial investigating water vapor therapy (Rezūm) treatment of moderate to severe lower urinary tract symptoms due to benign prostatic hyperplasia. The study included 197 patients over 50 years of age with International Prostate Symptom Score (IPSS)  $\geq 13$ , maximum flow rate  $\leq 15$  ml/second and prostate volume 30 to 80 cc. The number of vapor treatments applied to each prostate lobe was determined by length of prostatic urethra and included middle lobe treatment per physician discretion. Within three months, patients showed significant LUTS improvements, including a 48% reduction in IPSS, a 45% increase in quality of life, a 44% improvement in maximum urine flow rate, and a 48% decrease in BPH Impact Index. The surgical re-treatment rate was 4.4%, with no reported issues of sexual dysfunction or sustained erectile dysfunction related to the device or procedure. Authors concluded that minimally invasive treatment with water vapor thermal therapy provides significant symptom relief and flow rate improvements through 5 years, with low surgical re-treatment rates, and without impacting sexual function.

Woo et al. (2023) conducted a single-arm study to evaluate the safety and efficacy of water vapor thermal therapy in patients with symptomatic BPH and larger prostate glands, ranging from 80.8 to 148.1 cm<sup>3</sup>. The study included 47 participants over the age of 50 with prostate volumes greater than 80 cm<sup>3</sup> and up to 150 cm<sup>3</sup>. Using the Rezūm system, sterile water vapor was delivered via a transurethral approach to targeted areas of prostate tissue. The primary outcome measure was response to therapy, defined as at least a 30% improvement in IPSS at 6 months. The primary safety outcome was a composite of serious device-related adverse events. Secondary outcomes included catheterization rates due to device-related urinary retention. Results showed that all 47 patients completed a 6-month follow-up, with 40 patients also completing a 12-month follow-up. At 6 months, 83% of patients were treatment responders according to the primary efficacy endpoint. The mean IPSS improvement at 6 months was  $11.9 \pm 7.5$  points, reflecting a significant improvement in symptoms. The primary safety outcome was met, with no occurrence of device-related safety events. The study is limited by the nonrandomized design and early termination, unrelated to safety or effectiveness. Authors conclude the results are consistent with previous findings for prostate glands of up to 80 cm<sup>3</sup> and indicate the safety and efficacy of Rezūm for BPH in patients with a larger prostate.

### c. U.S. Food & Drug Administration (FDA) Information

VA generally only approves use of medical devices that have received at least FDA clearance for 510(k) Premarket Notification. The following device has received Premarket Approval from the FDA and is indicated for use in patients with above knee amputations.

To search for devices that have received FDA 510(k) clearance or Premarket Approval (PMA), please visit the [FDA Devices database](#).

Information	Description
Product Name	Rezūm System
PMA Applicant	Libra Medical, Inc.
Address	8401 73rd Avenue North, Suite 63 Brooklyn Park, MN 55428
Approval Date	08/27/2015
Approval Letter	<a href="#">K150786-213841.pdf (fda.gov)</a>

### d. Medicare Coverage Determinations

There are no available Medicare coverage determinations. VA and Medicare are governed by separate laws and regulations; thus, VA coverage determinations may be different.

## IV. Definitions

Term	Definition
Alpha Blocker	These medications block the alpha receptor on cells, resulting in the relaxation of the muscle of the prostate and bladder neck, allowing urine to flow more easily
Bacterial Prostatitis	An acute infection of the prostate gland that causes urinary tract symptoms and pelvic pain
Benign Prostatic Hyperplasia	A condition in which the prostate gland is enlarged and not cancerous
Dutasteride	A medication that helps shrink an enlarged prostate and improve urinary symptoms
Dysuria	The sensation of pain and/or burning, stinging, or itching of the urethra or urethral meatus associated with urination
Finasteride	A medication that blocks the body's production of a male hormone that causes the prostate to enlarge

Term	Definition
Indwelling Foley Catheter	A thin, flexible rubber or plastic tube that goes through the urethra into the bladder
International Prostate Symptom Score (IPSS)	A scoring system made up of 7 questions related to voiding symptoms - a score of 0 to 7 indicates mild symptoms, 8 to 19 indicates moderate symptoms, and 20 to 35 indicates severe symptoms
Neurogenic Bladder	A condition in which the patient lacks bladder control due to a brain, spinal cord, or nerve problem, usually as a result of a chronic disease
Nocturia	Waking up more than once during the night to urinate
Lower Urinary Tract Symptoms (LUTS)	Examples include leaking urine, having sudden and frequent urges to urinate, having a weak stream, or feeling like you can't empty your bladder
PDE <sub>5</sub> Inhibitor	Also called a phosphodiesterase inhibitor, PDE <sub>5</sub> inhibitor is a medication that results in smooth muscle relaxation of the bladder and prostate, improving urinary symptoms
Prostate Central Zone	Area surrounding the ejaculatory ducts and located posterior to the transition zone and the urethra
Prostate Medial Zone	A cone-shaped portion of the gland situated between the two ejaculatory ducts and the urethra
Prostate Zones	Four major areas of the prostate; the peripheral zone, the central zone, the transition zone, and the anterior fibromuscular stroma
Retrograde Ejaculation	When semen enters the bladder instead of emerging through the penis during orgasm
Transurethral	Passing through urethra
Urethra	The tube that connects from the bladder to the external environment and allows urine to flow out of the body
Urethral Stricture	Narrowing of the tube, or urethra, that carries urine out of the body

## V. References

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**VI. CDI History/Revision Information**

- Explanation of changes to the CDI

Revision Type	Date of Revision	Update(s) Made to CDI
	MM/DD/YYYY	
	MM/DD/YYYY	