Molina Clinical Policy
Water Vapor Thermal Therapy for Benign Prostatic Hyperplasia
Policy No. 384

Last Approval: 10/14/2026
Next Review Due By: October 2027

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment. Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the CMS website. References included were accurate at the time of policy approval and publication.

OVERVIEW

Benign prostatic hyperplasia (BPH) is one of the most common chronic conditions among middle-aged and elderly men, affecting nearly 70% of men in the United States between the ages of 60 and 69 and nearly 80% of men over 70. It is caused by a non-malignant overgrowth of non-malignant prostate cells that can lead to lower urinary tract symptoms (LUTS). The enlarged prostate restricts the urethra and applies pressure to the base of the bladder. This restriction of the urethra can result in urination difficulties (McVary 2025). BPH is typically diagnosed by the presence of storage and/or voiding LUTS (e.g., urinary frequency, urgency, nocturia, weak urinary stream, straining, intermittency, hesitancy, and postvoid dribbling) in the absence of history, examination, or laboratory findings suggesting non-BPH causes of LUTS. The primary goal of treatment of symptomatic BPH is to alleviate the bothersome LUTS attributed to BPH. Available BPH treatment options differ by degree of invasiveness, efficacy, and adverse event profiles ([1]McVary 2026).

Surgical treatment of symptomatic BPH has three general types: transurethral surgery, simple prostatectomy, and minimally invasive surgical therapies (MIST). Historically, transurethral resection of the prostate (TURP) has been considered the standard surgical intervention for BPH in men with small to medium-sized prostates; however, men undergoing TURP may develop complications. Less invasive techniques that can be performed as outpatient procedures have been developed in an attempt to reduce short- and long-term complications associated with more invasive procedures and preserve sexual function ([2]McVary 2026).

Water vapor thermal therapy (WVTT) is a MIST for the treatment of BPH that uses radiofrequency to generate water vapor at approximately 103°C. The vapor penetrates the interstitial spaces of the prostate tissue, disrupting cell membranes and inducing tissue necrosis. The **Rezūm System** is a MIST that consists of a radiofrequency power generator and a single-use delivery device. The rigid shaft of the delivery device contains a needle that injects wet thermal energy (i.e., steam) into the hyperplastic prostatic tissue. The steam immediately condenses to water, thereby dispersing thermal energy and killing the surrounding cells. The dead cells are eventually absorbed, which reduces the volume of prostatic tissue and opens the urethra. The total number of treatments in each lobe is based upon the length of the hyperplastic prostatic tissue and the length of the urethra, but typically 1 to 3 sites are treated per lobe. Potential risks associated with WVTT include but are not limited to dysuria, hematuria, hematospermia, decrease in ejaculatory volume, UTI, urinary frequency, and retention or urgency. In rare cases, narrowing of the bladder neck, bladder stone, or severe infection may occur (McVary et al. 2016).

Regulatory Status

The Rezūm System (Boston Scientific Corporation) received FDA clearance through the 510(k) pathway (K150786) in August 2015. The Rezūm System is classified by the FDA as a class II device, product code KNS (an endoscopic electrosurgical unit and accessories) and is regulated under 21 CFR 876.4300. In June 2025, the upper prostate-volume limit was expanded from 80 to 150 cm^3 under 510(k) submission K250584. According to the FDA, the Rezūm System is 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 ≥ 30 cm^3 and ≤ 150 cm^3. The Rezūm System is also indicated for treatment of prostate with hyperplasia of the central zone and/or median lobe.

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COVERAGE POLICY

Water vapor thermal therapy (WVTT) (e.g., Rezūm System) may be **considered medically necessary** for the treatment of symptomatic benign prostatic hyperplasia (BPH) when ALL the following clinical criteria are met:

1. The procedure is performed by a urologist who is experienced/trained in the use of the Rezūm system
2. Member is age 50 years or older
3. Diagnosis of symptomatic moderate to severe lower urinary tract symptoms (LUTS) including:
   a. International Prostate Symptom Score (IPSS) ≥ 13
   b. Maximum urinary flow rate (Qmax) of ≤15 mL/s (voided volume greater than 125 ml)
4. Documentation of prostate volume ≥ 30 cm^3 and ≤ 80 cm^3 by ultrasound or other radiologic assessment
5. Member has undergone appropriate testing to exclude diagnosis of prostate cancer
6. Documentation of ONE of the following:
   a. Member is not a suitable candidate for general anesthesia, or is unable to tolerate standard medical therapy
   b. Member has intolerance or labeled contraindication to medical therapy
   c. Inadequate response (defined as persistent or progressive LUTS after an appropriate trial period) to the following maximally titrated treatments and adequate trial period of at least 6 months, intolerance, or contraindication to therapy:
      i. Alpha adrenergic blockers (alfuzosin, doxazosin, silodosin, tamsulosin, and terazosin)
      ii. Phosphodiesterase type 5 (PDE5) inhibitors
      iii. 5-alpha reductase inhibitors (including finasteride, dutasteride, and dutasteride plus tamsulosin)
      iv. Combination medication therapy maximally titrated
7. Absence of ALL the following contraindications:
   a. Urinary sphincter implant
   b. Penile prosthesis
   c. Active UTI
   d. Known or suspected prostate cancer (based on NCCN Prostate Cancer Early Detection guidelines) or a prostate specific antigen (PSA) >10 ng/mL
   e. History of bacterial prostatitis in the past three months
   f. Prior prostate surgery
   g. Neurogenic bladder
   h. Active urethral stricture (i.e., the source of the current LUTS)

Continuation of Therapy
Repeat use of transurethral WVTT (after the completion of all initial treatments in each lobe – typically 1 to 3 sites are treated per lobe – based upon the length of the hyperplastic prostatic tissue and the length of the urethra) is not authorized. The safety and efficacy of repeat use of WVTT for BPH have not been evaluated and is not supported by peer-review literature. The evidence is insufficient to determine the effects of the technology on health outcomes

Limitations and Exclusions
The following are considered **experimental, investigational, and unproven** based on insufficient evidence:

1. Use of transurethral WVTT as a treatment of BPH in a patient with a diagnosis of prostate cancer
2. Use of transurethral WVTT as a treatment of BPH after use of other minimally invasive procedures for BPH (e.g., prostatic urethral lift)

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NOTE: *This policy addresses transurethral WVTT in the treatment of BPH only. Transurethral waterjet ablation (aquablation) is not addressed as a treatment of BPH in this policy*

DOCUMENTATION REQUIREMENTS: Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

Clinical experience with water vapor thermal therapy (WVTT) is widely reported and supported by relevant professional societies, including the American Urological Association and National Institute for Health and Clinical Excellence. The evidence in the peer-reviewed scientific literature provides consistent results suggesting that the Rezūm System may be an effective treatment for lower urinary tract symptoms (LUTS) associated with BPH. Improvements in urinary symptoms and BPH-related Quality of Life (QOL) from baseline were generally consistent across studies. Treatment with the Rezūm System has demonstrated a generally favorable safety profile, with preservation of sexual function reported across studies. Furthermore, outcomes from the pivotal randomized controlled trial (RCT) of 197 patients were sustained throughout the 5-year follow-up with no de novo erectile dysfunction reported, and no significant changes in International Index of Erectile Function-Erectile Function (IIEF-EF) or ejaculatory function scores compared to baseline (McVary et al. 2021). More recent RCTs have compared WVTT with pharmacologic therapy and transurethral resection of the prostate (TURP), although long-term comparative evidence remains limited. Evidence supporting WVTT in prostates exceeding 80 cm^3 consists predominantly of observational studies with relatively small patient populations and limited long-term follow-up. Additionally, many studies have received manufacturer funding and have involved investigators with financial relationships with Boston Scientific, the manufacturer of Rezūm, representing a potential source of bias.

Randomized Controlled Trials

Vincendeau et al. (2026) conducted a multicenter, open-label RCT comparing Rezūm WVTT to combination pharmacotherapy (CP) of an alpha blocker plus a 5-alpha-reductase inhibitor in sexually active men with symptomatic benign prostatic obstruction refractory to alpha-blocker monotherapy. A total of 151 men were randomized 1:1, to either WVTT (n = 75) or CP (n = 76). Mean age was 64.6 years in the WVTT group and 63.8 years in the CP group, while mean prostate volume was 62.1 mL and 62.4 mL, respectively. The primary endpoints were change in International Prostate Symptom Score (IPSS), for noninferiority and superiority, and Male Sexual Health Questionnaire (MSHQ) total score for superiority, with 1-year follow-up. At 12 months, IPSS improved by 10.8 $\pm$ 6.8 points in WVTT participants versus 6.2 $\pm$ 7.7 points in CP participants, for a between group difference of 4.6 points (97.5% confidence interval [CI] 1.6-7.6, $p < 0.001$). For WVTT participants, IPSS QOL scores improved by 2.7 $\pm$ 1.8 versus 1.8 $\pm$ 2.0 points in CP participants ($p = 0.01$). MSHQ scores were maintained in WVTT participants (+1.1 $\pm$ 16.9 points) and decreased (-5.2 $\pm$ 16.4 points) in CP participants. WVTT resulted in lower rates of surgical retreatment (1.3% vs 9.2%). IPSS worsening by ≥ 4 points occurred in 13% of CP participants versus 2.7% of WVTT participants. Required catheterization beyond 90 days occurred in 0% of WVTT participants and 1.3% of CP participants. WVTT had higher pharmacological retreatment rates (12% vs 1.3%). Treatment-related adverse events (AEs) were also more frequent with WVTT, with rates of 40% for AEs and 12% for serious AEs versus 28% and 1.3%, respectively, for CP participants. Six WVTT procedure-related serious AEs were reported and included 2 urinary retention events, 1 case of bacterial prostatitis, 1 case of prostatic obstruction, 1 case of persistent LUTS, and 1 case of anejaculation. Other common WVTT events included urinary retention/LUTS/hematuria (20/75 patients), infection (14/75 patients), and erectile dysfunction (2/75 patients). The authors concluded that the 1-year results support WVTT as an alternative to combination pharmacotherapy, providing greater symptom and QOL improvement while preserving sexual function, but longer-term follow-up is needed to determine if these benefits persist. The study was funded by Boston Scientific, the manufacturer of Rezūm.

Samir et al. (2024) conducted two-year follow-up of an RCT comparing the efficacy and safety of Rezūm WVTT with bipolar transurethral resection of the prostate (B-TURP). One hundred participants were randomized 1:1 to either WVTT (n = 50) or B-TURP (n = 50), with no reported loss to follow-up. Eligible participants were sexually active men aged 50-80 years with BPH, prostate volume of 50-120 mL, severe LUTS despite alpha-blocker treatment (IPSS > 20 and Qmax < 10 mL/S), and no prostate cancer, neurogenic bladder, urethral stricture, bladder stones, or previous

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prostate surgery. At 24 months, both treatments produced statistically significant improvements from baseline, but B-TURP produced greater improvements for most urinary outcomes. Mean IPSS decreased from baseline 23.7 to 10.7 with Rezūm versus 23.4 to 6.4 with B-TURP ($p < 0.001$). A marked response to therapy, defined as an IPSS improvement of $\geq$ 8 points, occurred in 82% of Rezūm patients versus 90% of B-TURP patients. Mean Qmax increased from a baseline of 8.7 mL/s to 14.1 mL/s with Rezūm versus an increase from 8.4 mL/s to 20.1 mL/s with B-TURP ($p < 0.001$). Post-void residual urine decreased from 108.2 mL to 52.6 mL for Rezūm versus 109.2 mL to 33.9 mL for B-TURP ($p < 0.001$). QOL scores, with lower scores representing improvement, declined from 4.6 to 2.0 for Rezūm versus 4.6 to 1.6 for B-TURP ($p < 0.001$). PSA decreased from 6.0 to 3.4 ng/mL and prostate size decreased from 71.9 to 51.9 g for Rezūm versus 6.2 to 2.0 ng/mL and 74.1 to 27.7 g, respectively, for B-TURP ($p < 0.001$). Sexual outcomes at 24 months favored Rezūm, with a mean Internation Index of Erectile Function of 13.6 $\pm$ 4.6 versus 11.5 $\pm$ 5.1 for B-TURP ($p = 0.005$). Complications were less frequent with Rezūm compared to B-TURP, with hematuria occurring in 4% versus 10% ($p = 0.025$), retrograde ejaculation in 2% versus 80% ($p < 0.001$), and severe erectile dysfunction in 2% versus 28% ($p = 0.002$). The authors concluded that for BPH with prostate sizes of 50-120 g, Rezūm was less effective than B-TURP for urinary outcomes over 2 years but produced significant symptom and QOL improvement with fewer complications and better preservation of erectile and ejaculatory function.

McVary et al. (2016) reported outcomes from a prospective, multicenter, double-blind RCT in which the Rezūm system was used to treat LUTS associated with BPH. This FDA-approval study included a total of 197 men aged 50 years or older with an IPSS of 13 or greater, maximum flow rate of 15 mL per second or less, and prostate size 30-80 cc. Patients were randomized 2:1 between thermal therapy with the Rezūm System (n = 136) and control procedure with rigid cystoscopy with simulated active treatment sounds (n = 61). Thermal water vapor was injected into the transition zone and median lobe as needed. After 3 months the study was unblinded. After unblinding, 53 of the 61 subjects elected and qualified to go to the treatment arm and received thermal therapy within the 6-month follow-up. There were 129 thermal treatment subjects included in the per protocol analysis at 6 months and 120 at 12 months. The primary outcome was the difference in the change from baseline between the treatment and control arms at 3 months post-treatment. The secondary outcome was the percentage of responders at 3 months. Response was defined as a 30% or greater improvement (reduction) in IPSS at 3 months compared to baseline. The Rezūm group showed an 11.2-point decrease in IPSS, versus a 4.3-point decrease in the sham group ($p < 0.001$). There were more responders in the Rezūm group. Notably, more than half of the patients in the control group were classified as responders at 3 months. There were significant differences in other measures of LUTS and QOL. Participants in the Rezūm group had an IPSS reduction of 22 points from baseline at 2 weeks post-treatment and by 50% or greater at 3, 6 and 12 months. The peak flow rate increased by 6.2 mL per second at 3 months and was sustained throughout 12 months. 130 of the 197 participants (70.0%) reported being sexually active at baseline and were assessed for erectile function. There were no significant changes in erectile or ejaculatory function at follow-up and no differences between groups. Notable AEs include two patients in the Rezūm group that experienced serious procedure-related AEs: one patient had de novo extended urinary retention and another had nausea and vomiting due to alprazolam and was hospitalized overnight for observation. Limitations of the study include the small sample size, short follow-up duration in the sham-controlled phase, no control group, lack of blinding of longer-term outcomes, and lack of comparison to alternative treatments such as TURP.

After unblinding at 3 months, control subjects who elected to proceed were requalified for the crossover study. McVary et al. (2019) reported 4-year outcomes of the RCT of WVTT for treatment of moderate to severe LUTS due to BPH. LUTS were significantly improved within ≤3 months for the 135 men initially treated with WVTT. The LUTS remained durable (IPSS 47%, QOL 43%, Qmax 50%, BPH Impact Index 52%) throughout the 4-year follow-up period. Urinary symptoms, flow rate, and QOL remained significantly improved from baseline up to 5 years. Over 5 years, the surgical retreatment rate was 4.4% and the medication retreatment rate was 11.1%. No AEs on erectile or ejaculatory function were observed, and no significant changes in IIEF-EF or ejaculatory function scores were observed compared to the baseline (McVary et al. 2021).

Systematic Reviews and Meta-Analyses

Farooq et al. (2026) conducted a systematic review and meta-analysis to compare WVTT outcomes in patients with large prostate volumes (> 80 cc) compared to average glands ($\leq$ 80 cc). The review involved 11 studies, including 7 retrospective and 4 prospective observational studies, with no RCTs, for a total of 2,091 patients. However, the strength of pooled findings contributing to the meta-analysis was limited by differences in reported outcomes and follow-up intervals, and small numbers of patients with large prostates. The primary effectiveness outcomes were changes from baseline in the IPSS and maximum urinary flow rate (Qmax) at 3 months, with additional assessments at 6 and 12

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months. At 3 months, pooled IPSS improvements were -9.9 ± 7.7 points in averaged sized prostates (n = 159) and -11.2 ± 8.9 points in large prostates (n = 61). Comparative meta-analysis found no statistically significant difference in IPSS improvement between prostate size groups at 3 months (p = 0.29), 6 months (p = 0.61), or 12 months (p = 0.36). At 3 months, Qmax increased by 5.1 ± 6.7 mL/s in average-sized prostates (n = 220) and 7.2 ± 8.9 mL/s in large prostates (n = 109). Between-group differences were not statistically significant at 3 months (p = 0.12) or 12 months (p = 0.59). However, large prostate patients demonstrated significantly greater Qmax improvement at 6 months with a difference of 3.94 mL/s (95% CI 10.00-6.89, p = 0.009). Additional findings included improvements in IPSS QOL scores and postvoid residual volume (PVR) and reductions in BPH medication use regardless of prostate size. Urinary tract infection rates ranged from 2.4%-15.6% in average-sized prostates and 0%-19.4% in large prostates, with no significant difference between groups. One study reported significantly higher rates of sepsis (5.6% vs 0%, p = 0.002) and urinary urgency (50% vs 30.4%, p = 0.024) in large prostate patients. Other adverse events, including hematuria, bleeding, urinary retention, and postoperative catheterization were generally comparable between groups. The authors rated the overall risk of bias as moderate with a certainty of evidence ranging from very low to moderate. Important limitations include exclusively observational evidence, relatively small number of patients with large prostates, limited follow-up, and insufficient long-term data. The authors concluded that WVTT provides comparable improvements in urinary symptoms, urinary flow, and QOL in patients with large and average-sized prostates without an overall increase in complications but emphasized the need for high-quality RCTs and longer-term studies to establish the safety and efficacy in patients with large prostates. Multiple authors were employees or paid consultants of Boston Scientific, the manufacturer of Rezūm.

Li et al. (2026) conducted an umbrella systematic review and meta-analysis to evaluate the safety and efficacy of WVTT in men with BPH. The review included 6 systematic reviews, of which 3 contained meta-analyses, while the updated meta-analysis included 25 primary studies (1 RCT, 3 prospective trials, and 21 retrospective studies) for a total of 3,308 patients. The primary outcome was improvement in the IPSS, with secondary outcomes including peak urinary flow (Qmax), PVR, complications, and retreatment rates. Meta-analysis demonstrated statistically significant improvements in urinary symptoms and objective function following WVTT. At 3 months, IPSS decreased by a mean of 10.96 points (95% CI 9.71-12.20, p < 0.0001, I^2 = 89%), Qmax increased by 4.70 mL/s (95% CI 4.22-5.19, p < 0.00001, I^2 = 31%), and PVR decreased by 69.52 mL (95% CI 52.15-86.89, p < 0.00001), I^2 = 84%). At 12 months, IPSS decreased by 12.35 points (95% CI, 10.74-13.95, p < 0.00001, I2 = 94%), Qmax increased by 5.27 mL/s (95% CI 4.46-6.07, p < 0.00001, I2 = 84%), and PVR decreased by 37.07 mL (95% CI 18.29-55.85, p = 0.0001, I^2 = 97%). There were 980 cases of AEs, with the most frequent being hematuria (16.46%), urinary retention (11.2%), dysuria (9.85%), and urinary tract infection (5.88%). Less frequent complications included prostate tissue sloughing (2.49%), erectile dysfunction (2.06%), hemospermia (1.41%), and retrograde ejaculation (0.40%). While the umbrella review indicated that WVTT generally preserved sexual function, an updated meta-analysis could not be performed because of incomplete outcome data. Retreatment rates in the umbrella review ranged from 1.2% to 4.4% and the authors noted that evidence regarding long-term retreatment outcomes remains limited. Limitations include the predominance of single-arm observational and retrospective studies, only 3 primary studies reporting follow-up beyond 12 months, and significant statistical heterogeneity. The 6 systematic reviews received AMSTAR 2 ratings of low or critically low, while GRADE evidence ratings were predominantly low or very low. The authors concluded that WVTT is a safe and effective minimally invasive treatment option for BPH, providing improvements in urinary symptoms and function, generally preserving sexual function, and demonstrating low retreatment rates. Additional high-quality prospective studies with larger populations, longer follow-up periods, and direct comparisons with other surgical treatments are needed to establish long-term efficacy and comparative effectiveness.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Woo et al. (2024) conducted a prospective, multicenter, single-arm clinical trial to evaluate the safety and efficacy of Rezūm WVTT for treating LUTS associated with BPH in men with larger prostates (> 80 to ≤ 150 cm^3). The trial included 47 participants with a median prostate volume of 92.9 cm^3 (range 80.8-148.1 cm^3) and median age of 68 years. All participants completed the 6-month follow-up while only 40 completed the 12-month follow-up. The primary efficacy endpoint was treatment response at 6 months, defined as freedom from surgical retreatment and a ≥ 30% improvement in IPSS from baseline, while the safety endpoint was a composite of predefined serious device-related complications. At 6 months, 83% of participants (95% CI 69.2-92.4%) achieved the primary efficacy endpoint. Mean IPSS decreased from 20.6 ± 5.2 at baseline to 8.7 ± 7.4 points. At 12 months, 69% of participants (95% CI 52.9-82.4%) achieved an IPSS improvement of ≥ 8 points from baseline. Maximum urinary flow rate (Qmax) increased by a mean of 7.1 ± 7.0 mL/s at 12 months (95% CI 4.9-9.3), while mean PVR decreased by 32.1 mL. For secondary outcomes, IPSS QOL improved as demonstrated by mean reductions of 3.0 points and 5.0 points in the BPH Impact Index at 12

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months. No patients required surgical retreatment at 6 months, and 6.4% of patients were treatment failures because they continued alpha blocker medication beyond the permitted 120-day period. The primary safety endpoint was met. There were 2 serious procedure-related AEs, with 1 case of acute prostatitis requiring antibiotics and 1 case of gross hematuria with clots and urinary retention requiring cystourethroscopy with clot evacuation. There were also 164 nonserious AEs reported among 91.5% of patients by their last follow-up visit. The most common included gross hematuria (25.5%), culture-confirmed urinary tract infection (23.4%), urinary urgency (21.3%), bladder spasms (21.3%), dysuria (21.3%), acute urinary retention (14.9%), worsening erectile dysfunction (6.4%), anejaculation (4.3%), decreased ejaculatory volume (4.3%), new-onset erectile dysfunction (2.1%), and retrograde ejaculation (2.1%). Study limitations include the nonrandomized, uncontrolled design, small sample size, and premature study termination. The authors concluded that Rezūm WVTT was safe and effective in men with larger prostate volumes of 80-150 cm^3. The study was funded by Boston Scientific, the manufacturer of Rezūm.

National and Specialty Organizations

The **American Urological Association** updated its clinical guideline, *Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia* ([1-3]Goueli et al. 2026), which provides evidence-based recommendations for the management of male LUTS secondary to BPH. The guideline has undergone periodic reviews and updates as new evidence has emerged, with the most recent update in 2026 providing the following recommendations:

- *Pharmacologic Therapy Recommendations*
  - Alpha Blockers
    - Clinicians should offer one of the following alpha blockers as a treatment option for patients with LUTS/BPH: alfuzosin, silodosin, or tamsulosin (Moderate to Strong Recommendation; Evidence Level: Grade A).
    - When prescribing an alpha blocker for the treatment of LUTS/BPH, clinicians should counsel patients regarding different AE profiles and select treatment based on patient preference and comorbidities (Clinical Principle).
  - Phosphodiesterase-5 Inhibitor (PDE5)
    - For patients with LUTS/BPH, irrespective of comorbid erectile dysfunction, clinicians should offer 5 mg daily tadalafil (Moderate Recommendation; Evidence Level: Grade B)
  - 5- Alpha Reductase inhibitor (5-ARI)
    - For symptom improvement, clinicians should offer 5-ARI to patients with LUTS/BPH and an estimated prostate volume of > 30cc and/or PSA > 1.5 ng/mL (Moderate Recommendation; Evidence Level: Grade A).
    - Clinicians may offer 5-ARI therapy to patients with LUTS/BPH and an estimated prostate volume > 30 cc and/or PSA > 1.5 ng/mL to reduce the risk of clinical BPH progression, including worsening symptoms, acute urinary retention, or the need for BPH surgery (Clinical Principle).
    - Clinicians should offer a 5-ARI in combination with an alpha blocker as a treatment option for patients with LUTS/BPH and an estimated prostate volume > 30 CC and/or PSA > 1.5 ng/mL (Moderate Recommendation; Evidence Level: Grade B).
- *Water Vapor Thermal Therapy Recommendations*
  - Clinicians should offer WVTT as a treatment option for patients with LUTS attributed to BPH and prostate volumes of 30-80 cc (Moderate Recommendation; Evidence Level: Grade B)

The **National Institute for Health and Clinical Excellence (NICE)** (2020) [HTG545] concluded that the evidence base supports the utilization of Rezūm for the treatment of LUTS secondary to BPH. The guidance notes that "evidence supports the case for adopting Rezūm for treating LUTS caused by BPH in the National Health Service. Rezūm relieves LUTS and improves quality of life." Rezūm is a minimally invasive procedure and should be considered as a treatment option for people with:

- Moderate to severe LUTS (IPSS typically 13 or over)
- A moderately enlarged prostate (typically between 30 cm^3 and 80 cm^3)
- Cost modelling estimates that Rezūm is cost saving compared with standard treatments, like TURP

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CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

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

CODING DISCLAIMER: Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

10/14/2026	Policy reviewed. No changes to coverage criteria.
10/08/2025	Policy reviewed. No changes to coverage criteria. IRO peer reviewed on September 25, 2025 by a practicing physician board certified in urology.
10/09/2024	Policy reviewed. No changes to coverage criteria.
12/13/2023	Policy reviewed. No changes to coverage criteria.
12/14/2022	Policy revised. Revision of coverage criterion. IRO Peer Review 11/2022 by a practicing physician board-certified in Urology. Notable revisions include: defining 'symptomatic' moderate to severe LUTS International Prostate Symptoms Score (IPSS) ≥ 13 or over; AND Maximum urinary flow rate (Qmax) of ≤15 mL/s (voided volume greater than 125 cc). Updated 'Limitations and Exclusions' criteria to add the following: Known or suspected prostate cancer (based on NCCN Prostate Cancer Early Detection guidelines) or a prostate specific antigen (PSA) >10 ng/mL, History of bacterial prostatitis in the past three months, Prior prostate surgery, Neurogenic bladder, and Active urethral stricture (i.e., the source of the current LUTS).
12/08/2021	Policy revised. Notable revisions include: Broadened policy from 'Rezūm System for Benign Prostatic Hyperplasia' to 'Transurethral Water Vapor Thermal Therapy for BPH' to address WVTT treatments, which includes the Rezūm System. Policy title revised from 'Rezūm System for Benign Prostatic Hyperplasia' to 'Transurethral Water Vapor Thermal Therapy for BPH'; Coverage revised from 'experimental, investigational and unproven' to medically necessary with medical necessity criteria in accordance with current clinical evidence, peer-review literature with consideration from professional society recommendations. IRO Peer Review Nov 2021 by a practicing physician board-certified in urology.
12/09/2020	New Policy. IRO Peer Review 10/5/2020. Reviewed by practicing physician board-certified in Urology.

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