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

Last Approval: 12/13/2023
Next Review Due By: December 2024

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. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Benign Prostate Hypertrophy (BPH) is one of the most prevalent chronic conditions among middle-aged and elderly men, affecting approximately 60% of men aged 60 years and older in the United States. It is caused by the abnormal growth of non-malignant prostate cells that can result in bothersome 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. BPH is typically diagnosed by the clinical features, including an enlarged prostate and mild-to-severe lower LUTS (e.g., urinary obstruction or retention, weak stream and straining, urinary urgency and frequency, renal insufficiency, hydronephrosis, recurrent gross hematuria, recurrent or persistent urinary tract infections (UTIs), urosepsis, large bladder diverticula, and bladder stones). The primary goal of treatment of symptomatic BPH has been to alleviate the bothersome LUTS that result from benign prostatic obstruction. Available BPH treatment options differ by degree of invasiveness, efficacy, and adverse event (AE) profiles (AUA Guideline Part II 2021) .

Surgical treatment of symptomatic BPH has three general types: 1) Transurethral surgery; 2) Simple prostatectomy; and 3) Minimally invasive surgical therapies (MIST) (AUA Guideline Part II 2021). 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 serious AEs. Less invasive techniques that can be performed as outpatient procedures have been developed in an attempt to reduce short- and long-term complications and preserve sexual function that may be associated with more invasive procedures.

Water vapor thermal therapy (WVTT) is a minimally invasive surgical intervention for treating BPH that uses radiofrequency to generate water vapor (~103°C) that penetrates prostate tissue interstices and disrupts tissue cell membranes, resulting in necrosis. The **Rezūm System** is a MIST that consists of a radiofrequency power generator and is intended for single use. The rigid shaft of the delivery device contains a needle that injects wet thermal energy (i.e., steam) into the diseased 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 Rezūm Water Vapor Therapy 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 (the area of the bladder that connects to the urethra), 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. 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 ≤ 80 cm^3. The Rezūm System is also indicated for treatment of prostate with hyperplasia of the central zone and/or median lobe.

COVERAGE POLICY

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

1. Prescriber is a urologist and administration of the requested procedure is intended by a urologist who is experienced/trained in the use of the Rezūm system; **AND**
2. Age 50 years or older; **AND**
3. Diagnosis of symptomatic moderate to severe lower urinary tract symptoms (LUTS) including:
   a. International Prostate Symptoms Score (IPSS) ≥ 13; **AND**
   b. Maximum urinary flow rate (Qmax) of ≤15 mL/s (voided volume greater than 125 cc).

AND

4. Documentation of prostate volume ≥ 30 cm^3 and ≤ 80 cm^3 by ultrasound or other radiologic assessment; **AND**
5. Member has undergone appropriate testing to exclude diagnosis of prostate cancer; **AND**
6. Documentation of **ONE** of the following as applicable to member:
   a. Member is not a suitable candidate for general anesthesia, or is unable to tolerate standard medical therapy; **OR**
   b. Member has intolerance or labeled contraindication to medical therapy; **OR**
   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, OR intolerance or labeled contraindication to therapy:
      a. Alpha adrenergic blockers (alfuzosin, doxazosin, silodosin, tamsulosin, and terazosin)
      b. Phosphodiesterase type 5 (PDE5) inhibitors
      c. 5-alpha reductase inhibitors (including finasteride, dutasteride, and dutasteride plus tamsulosin)
      d. Combination medication therapy maximally titrated.

AND

7. Member does not have a urinary implant, penile prosthesis, or an active urinary tract infection (UTI) or prostatitis.

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

WVTT (e.g., Rezūm System) is **contraindicated and may not be authorized** if **ANY** of the following circumstances are present:

1. Urinary sphincter implant
2. Penile prosthesis
3. Active UTI
4. Known or suspected prostate cancer (based on NCCN Prostate Cancer Early Detection guidelines) or a prostate specific antigen (PSA) >10 ng/mL
5. History of bacterial prostatitis in the past three months

6. Prior prostate surgery
7. Neurogenic bladder
8. Active urethral stricture (i.e., the source of the current LUTS)

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

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

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 (AUA) and National Institute for Health and Clinical Excellence (NICE). 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 is reported as generally safe and not associated with loss of sexual function. Furthermore, outcomes from the 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 were observed compared to the baseline (McVary et al. 2021). However, no studies have compared WVTT (e.g., Rezūm System) to medical management, TURP, or other minimally invasive procedures.

McVary et al. (2016) reported outcomes from a prospective, multicenter, double-blind randomized control trial (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 International Prostate Symptoms Score (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).

Miller et al. (2020) conducted an industry-funded systematic review and meta-analysis of WVTT for the treatment of symptomatic BPH. Five cohorts treated with WVTT from 4 studies were reviewed (514 patients; 40% with median lobe obstruction) with 2 years median follow-up (range of 6 months to 4 years). The review found that IPSS, IPSS QOL, BPH impact index, and maximum flow rate were all improved from baseline with improvements seen at all intervals between 3 months and 4 years. Surgical re-treatment rates were 2.4% at year one, 5.3% at year 2, 6.3% at year 3, and 7.0% at year 4 of follow-up. Most AEs were not serious and transient; dysuria, urinary retention, and UTI were most common. No cases of de-novo ED occurred. The authors concluded that WVTT provided improvement in BPH symptoms that exceeded established MCID thresholds, preserved sexual function, and was associated with low surgical re-treatment rates over 4 years. It should be noted that while these findings suggested that the WVTT procedure may be a valuable addition to the urological treatment options for LUTS in men with BPH, the authors acknowledged that this meta-analysis had several limitations. One limitation was the follow-up period of the studies with few studies providing long term data. Patients in the included studies typically had a prostate volume less than 80 cc; therefore, WVTT efficacy and safety in larger prostates is unclear. The adverse event reporting was inconsistent among studies, so it is unclear if complication under-reporting may have occurred. Finally, most control patients across the studies elected to cross-over to WVTT at 3 months due to insufficient symptom relief. Aside from this 3-month period in a single study, direct comparative data with a control group or other BPH treatments are not available.

Yang et al. (2023) conducted a systematic review single-arm meta-analysis of seven single-arm observational studies and one RCT including 1015 patients with moderate to severe LUTS secondary to BPH. Primary outcomes measured included IPSS, IPSS QOL, PVR, and Qmax. Incidence of complications including hematuria, dysuria, hematospermia, UTI and pelvic pain were measured as secondary outcomes. In primary outcomes, IPSS, QOL and Qmax were significantly improved at six months after WVTT. IPSS decreased by 11.37 (95% Confidence Interval: -12.53, -10.21), IPSS QOL decreased by 2.59 (95% CI: -2.92, -2.26), Qmax rate increased by 5.26 mL/s (95% CI: 4.53, 5.99), and PVR decreased by 13.18 mL (95% CI: -24.32, -2.03). The most common complication was dysuria, with an incidence of 21% (95% CI: 14%, 29%), and the second most common complication was hematuria, with an incidence of 14% (95% CI: 10%, 18%). The incidence of retreatment was 3% (95% CI: 2%, 5%), which showed an advantage compared to TURP at 8%. Most complications reported occurred within 3 months and resolved within 3 weeks. Limitations of the review include not comparing the differences between WVTT and other treatment modalities for BPH as only one RCT was included in the study and the remaining studies were single-arm trials that lacked controls. Another limitation was that the meta-analysis included a small number of studies with small sample size. Some studies were not included in the meta-analysis according to screening criteria, which may have introduced bias. This systematic review and meta-analysis provide further insight that WVTT can provide significant efficacy in the treatment of BPH.

National and Specialty Organizations

American Urological Association

The AUA guidelines published in 2018 (amended 2019, 2020) provides evidence-based recommendations for the surgical management of male LUTS secondary to BPH. The guideline has undergone periodic reviews and updates as new evidence emerge with the most recent update in 2021 with the following recommendations:

- WVTT should be considered as a treatment option for patients with LUTS attributed to BPH provided prostate volume 30-80cc (Moderate Recommendation; Evidence Level: Grade C).
- WVTT may be offered as a treatment option to eligible patients who desire preservation of erectile and ejaculatory function (Conditional Recommendation; Evidence Level: Grade C).
- Robotic waterjet treatment may be offered as a treatment option to patients with LUTS/BPH provided prostate volume is 30 to 80 cc (Conditional Recommendation; Evidence Level: Grade C).

Pharmacologic Therapy Recommendations

Alpha Blockers

- Clinicians should offer one of the following alpha blockers as a treatment option for patients with bothersome, moderate to severe LUTS/BPH: alfuzosin, doxazosin, silodosin, tamsulosin, or terazosin (Moderate Recommendation; Evidence Level: Grade A).
- When prescribing an alpha blocker for the treatment of LUTS/BPH, the choice of alpha blocker should be based on patient age and comorbidities, and different AE profiles (e.g., ejaculatory dysfunction, changes in blood pressure) (Moderate Recommendation; Evidence Level: Grade A).

Phosphodiesterase-5 Inhibitor (PDE5)

- For patients with LUTS/BPH irrespective of comorbid erectile dysfunction, 5mg daily tadalafil should be discussed as a treatment option (Moderate Recommendation; Evidence Level: Grade B).

5- Alpha Reductase inhibitor (5-ARI)

- For the purpose of symptom improvement, 5-ARI monotherapy should be used as a treatment option in patients with LUTS/BPH with prostatic enlargement as judged by a prostate volume of > 30cc on imaging, a prostate specific antigen (PSA) > 1.5ng/dL, or palpable prostate enlargement on digital rectal exam (Moderate
- Recommendation; Evidence Level: Grade B).
  5-ARIs alone or in combination with alpha blockers are recommended as a treatment option to prevent progression of LUTS/BPH and/or reduce the risks of urinary retention and need for future prostate-related surgery. (Strong Recommendation; Evidence Level: Grade A).

The **National Institute for Health and Clinical Excellence (NICE)** 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 (International Prostate Symptoms Score [IPSS] typically 13 or over), and
- A moderately enlarged prostate (typically between 30 cm^3 and 80 cm^3).

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Code

CPT	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

12/13/2023 Policy reviewed. Updated references and summary of medical evidence.
12/14/2022 Policy reviewed and revised. Revision of coverage criterion. IRO Peer Review 11/2022 by a practicing physician board-certified in Urology. Notable revisions include:
1) #3 to define 'symptomatic' moderate to severe LUTS with #a and #b
   From: Diagnosis of moderate to severe LUTS (International Prostate Symptoms Score [IPSS] typically 13 or over)
   To: Diagnosis of symptomatic moderate to severe LUTS including:
   a. International Prostate Symptoms Score (IPSS) ≥ 13 or over; AND
   b. Maximum urinary flow rate (Qmax) of ≤15 mL/s (voided volume greater than 125 cc).
2) 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
- Active urethral stricture (i.e., the source of the current LUTS)

12/8/2021 Policy reviewed and revised. IRO Peer Review: 11/29/2021; 11/30/2021. Practicing physician board-certified in urology.

- 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'
- Procedure revised from 'experimental, investigational and unproven' to medically necessary with medical necessity criteria in accordance with current clinical evidence, peer-review lit. with consideration from professional society recommendations.
- Revised Summary of Evidence section; Updated RCTs: McVary et al (2018), McVary et al (2019), and McVary et al (2021). Added systematic review and meta-analysis (2020) and Cochrane review (2020). Updated AUA guidelines to most recent amendment in 2021; added NICE 2020 guidelines
- Added CMS information to 'Appendix' section

12/9/2020 New Policy. IRO Peer Review 10/5/2020. Reviewed by practicing physician board-certified in Urology.

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APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*