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

Last Approval: 12/14/2022
Next Review Due By: December 2023

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 (Parsons et al. 2020). 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 (AUA Guideline Part 2, 2021). Available BPH treatment options differ by degree of invasiveness, efficacy, and adverse event (AE) profiles. First-line therapy for patients with moderate-to-severe LUTS is often pharmacotherapy to relieve and limit the progression of symptoms (Parsons et al. 2020). However, adherence rates are low, with only one-third of patients adhering to the prescribed pharmacological treatment regimen for a duration longer than 6 months (Zabkowski 2018). Generally, pharmacotherapy provides minimal alleviation, with 25% to 30% of patients opting for surgical alternatives. (Hayes 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 2, 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 (Sun et al. 2018). TURP is an inpatient procedure that requires general or spinal anesthesia and has a high risk of complications. 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 surgical or more invasive procedures. Open prostatectomy is the standard surgical procedure for BPH in men with large prostates and is an invasive procedure in which part, or all of the prostate is removed (Sadri et al., 2021; Hayes). **Water vapor thermal therapy (WVTT)** is a relatively new 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 (McVary et al., 2016a). In short, WVTT uses steam (convective water vapor energy) to remove prostatic tissue. The procedure can be performed in the office with little anesthetic or pain medication required.

The **Rezūm System** is a MIST that uses water vapor-based (steam) convective thermal therapy to ablate hyperplastic tissue and treat LUTS associated with BPH. The technology uses water vapor to destroy excess prostate tissue and damage the cells that cause the overgrown prostate and urethral obstruction, thereby shrinking the prostate. The procedure is typically performed in a physician's office, clinic, or other outpatient setting and does not require hospitalization except in the case of a necessitating AE (McVary et al., 2016a). The Rezūm System 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, suspected 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.

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. The FDA indications for use include that 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.

Rezūm has been tested in 3 clinical studies to evaluate the safety and effectiveness of the device: 65 patients in the feasibility and pilot open label studies (FDA 510(k) Summary: Rezūm FIM Optimization Study; Rezūm I Pilot Study) and in a 197-patient randomized placebo-controlled study (Rezūm II study; McVary et al. 2016a). These studies indicated the device is safe and effective.

Centers for Medicare & Medicaid Services (CMS)

No National Coverage Determination (NCD) specific to BPH was identified on October 2022 (searched CMS Advanced Search Database by keywords LUTS, *lower urinary tract symptoms*, *BPH*, *benign prostatic hyperplasia*, *Rezūm*, *or water vapor* in all documents). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

COVERAGE POLICY

WVTT (e.g., Rezūm System) **may be considered medically necessary** for the treatment of symptomatic 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 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).

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 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

The evidence includes one 3-month, sham-controlled RCT of 197 patients with a 5-year uncontrolled follow-up phase. The outcomes reported include symptoms, quality of life (QOL), and treatment-related morbidity (McVary et al.2016a). At 3 months, LUTS 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 5 years of follow-up (McVary et al. 2021). Based on data from this pivotal study, ejaculatory function was preserved; however, men with BPH are at

higher risk for other potential urinary/ejaculatory challenges and there is a possibility that an underlying condition may surface following treatment with the Rezūm System (McVary et al.2016a). However, 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 TURP.

Clinical experience with WVTT is widely reported and supported by relevant professional societies, including the AUA and NICE. The evidence in the peer-reviewed scientific literature provides consistent results suggesting that the Rezūm System may be an effective treatment for LUTS associated with BPH. Improvements in urinary symptoms and BPH-related 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 (Dixon, et al., 2015b, 2016; McVary, et al., 2016a; Darson, et al., 2017; Roehrborn, et al., 2017b; McVary and Roehrborn, 2018; Miller et al. 2020). Furthermore, outcomes from the RCT of 197 patients showed were sustained throughout the 5-year follow-up with no de novo erectile dysfunction was 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. A Cochrane Review found only one study that compared convective WVTT and a sham procedure and found no studies that compared convective WVTT to TURP, laser ablation of the prostate, laser enucleation of the prostate, other minimal invasive therapies, or simple prostatectomy were found (Kang et al. 2020).

Randomized Controlled Trials (RCTs)

Transurethral WVTT has been evaluated in one RCT conducted in 197 men. Three-month results were reported in McVary et al (2016). The trial also had an uncontrolled, open-label crossover phase. After unblinding at 3 months, control subjects who elected to proceed were requalified for the crossover study. A total of 97 patients were followed through 3 years and 90 patients through 4 years. Three-year results were reported in McVary et al. (2018), and 4-year results in McVary et al (2019) and the 5-year follow-up reported in McVary et al. (2021).

McVary et al. (2016a) reported outcomes from a prospective, multicenter, double-blind RCT (Rezūm II study) using transurethral prostate convective water vapor thermal energy 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 (95.6% of 135) 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) int he IPSS at 3 months compared to baseline. The Rezum group showed an 11.2-point decrease in IPSS, vs a 4.3-point decrease in the sham group ($p<0.001$). There were more responders (defined as 30% or more improvement in the IPSS) in the Rezum 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. That is, the treatment was not associated with AEs on erectile or ejaculatory function. Notable AEs include 2 patients in the Rezum group that experienced 3 serious procedure-related AEs: 1 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. (Clinicaltrials.gov: NCT01912339)

The trial had an uncontrolled, open-label crossover phase, reported in McVary et al. (2018), McVary et al (2019), and McVary et al (2021). After unblinding at 3 months, control subjects who elected to proceed were requalified for the crossover study. A total of 98 patients were followed through 60 months. Urinary symptoms 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%.

McVary et al., (2019) reported 4-year outcomes of the RCT of WVTT for treatment of moderate to severe LUTS due to BPH. According to this study, '188 subjects; 135 men ≥50years old, IPSS ≥ 13, maximum flow rate (Qmax) ≤15 mL/s and prostate volume 30 to 80 cc treated with Rezūm System thermal therapy were followed 4 years; subset of 53 men who requalified for crossover from control to active treatment were followed 3 years. LUTS were significantly improved within ≤3 months after thermal therapy and remained consistently durable (IPSS 47%, QOL 43%, Qmax 50%, BPH Impact Index 52%) throughout 4 years; outcomes were similarly sustained in crossover subjects at 3years. Surgical retreatment rate was 4.4% over 4 years. No disturbances in sexual function were reported. The authors indicated that minimally invasive thermal therapy provides effective symptom relief and improved QOL that remains durable for over 4 years. It is applicable to all prostate zones with procedures performed under local anesthesia in an office setting.' This study is limited by small sample size.

McVary et al. (2021) reported on the five-year follow-up of the multicenter trial of 197 men randomized in a 2:1 ratio to treatment with WVTT or sham control (McVary et al. 2016a). At 3 months, response to vapor treatment was significantly greater than to sham cystoscopy (74 versus 31%). The flow rate increased from 9.9 mL/sec to 16.1 mL/sec after WVTT compared with an increase from 10.4 mL/sec to 10.8 mL/sec in control patients. The outcomes were sustained throughout the 5-year follow-up. No AEs on erectile or ejaculatory function were observed, 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).

Dixon et al. (2015, 2016) reported the one- and two-year clinical outcomes of thermal therapy using convective radiofrequency WVTT with the Rezūm System. The multicenter nonrandomized prospective pilot study included 65 men ≥45 years of age (mean prostate volume: 48.6 ± 20.5 cm3) with moderate (32%) to severe (68%) LUTS (mean IPSS: 21.6±5.5; mean Qmax: 7.9±3.2 mL/s). Urinary symptom relief, urinary flow, QOL impact, sexual function, and AEs were assessed. A total of 43/65 (66%) individuals provided data up to two years. Clinically and statistically significant improvements in urinary symptoms (-6.5-point IPSS reduction from baseline), flow rate (2.0-point increase), and quality-of-life measures were evident as early as one month after treatment. The treatment responses were optimal at 3-12 months (-12.6-point IPSS reduction from 21.6 at baseline to 9.2; a 4.6-point Qmax increase from 7.9 at baseline to 12 mL/s), these responses remained consistent and significant over 24 months of follow-up. Both storage and voiding components of the IPSS showed significant improvements. No clinically significant changes in sexual function were reported in this study and no de novo erectile dysfunction occurred. Results suggested that the Rezūm System significantly improved LUTS without negative impact on sexual function. Complications were mild-to-moderate and transient in nature. Reinterventions with Rezūm occurred in 7.7% of patients. Study limitations included lack of comparison group; small sample size and high attrition at 2-year follow-up.

Darson et al. (2017) conducted a retrospective observational multicenter study (n=131) to report clinical outcomes with the Rezūm system in consecutive cases accrued by multiple community urologists for the treatment of moderate to severe LUTS associated with BPH. According to this study, 'Follow-up was 12 months and there was no comparator. Pre- and post-procedure assessments included IPSS, QOL, peak urinary flow rate, voided volume, and post void residual urine volume. Urologists used their own discretion for patient selection, with variable prostate sizes, LUTS severity, urinary retention, or presence of an obstructing median lobe. Safety signals and surgical retreatment rates were monitored prospectively. There were significant reductions in IPSS scores (p0.05), except for Qmax 3-6 months, all patients and moderate LUTS. Post-procedure AEs normally anticipated and related to endoscopic instrumentation were transient and mild–moderate in nature.' This study is limited by lack of a comparator and short-term follow-up.

Ongoing and Unpublished Clinical Trials

C.L.E.A.R. - Comparing UroLift Experience Against Rezum (NCT04338776) (n=120)
Estimated Study Completion Date: December 2023

Systematic Reviews and Meta-Analyses

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 (improvement was 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. First, there was less precision in the results with extended follow-up since fewer studies with longer term data were available. Additional studies would improve the reliability of the meta-analysis estimates. Second, the number of included studies was insufficient to evaluate publication bias or sources of heterogeneity with only 1 randomized study, and only participants receiving WVTT were included in analysis. The other 4 studies were small, had short follow-up and high heterogeneity. There was no comparator, and no conclusions can be made about the efficacy of WVTT compared to standard of care treatments. Third, patients in the included studies typically presented with a prostate volume no larger than 80 cc and, therefore, the safety and effectiveness of WVTT in larger prostates were unclear. A clinical trial of WVTT for prostate sizes between 80 and 150 cc is ongoing, but results are not yet unavailable. Fourth, retrospective enrollment, unclear inclusion criteria, and limited follow-up duration were aspects of certain studies that may limit interpretability of results. Fifth, AE reporting was inconsistent among studies, and it was unclear if complication under-reporting may have affected the accuracy of the estimates. Development of consistent and comprehensive AE reporting standards for use in future trials of minimally invasive BPH therapies is needed. Finally, although 1 study utilized a sham control, most control patients 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. The authors recommended that comparisons of results with WVTT versus treatments such as PUL or TURP should be interpreted with caution (Miller et al. 2020).

Kang et al. (2020) conducted a Cochrane review of transurethral WVTT for management of LUTS in men with BPH. The authors conducted a comprehensive search of multiple databases (*including the Cochrane Library, Medline, Embase, Latin American and the Caribbean Health Sciences Literature, Scopus, Web of Science*), trials registries, other sources of grey literature, and conference proceedings published up to February 2020 with no restriction on the language or status of publication. In literature searches conducted through February 2020, the reviewers identified only one RCT (McVary et al. 2016a). The authors found no evidence for other comparisons, such as convective radiofrequency WVTT versus TURP or other minimal invasive procedures. The authors concluded that compared to a sham procedure, urologic symptom scores and QOL appeared to improve with convective radiofrequency WVTT, however, they were very uncertain regarding major AEs. These researchers did not find any studies comparing convective radiofrequency WVTT to any other active treatment form, such as TURP. The reviewers concluded that there was moderate-to low-certainty evidence that the procedure appears to improve urologic symptom scores and QOL compared to a sham procedure. However, there was very low certainty of evidence about the effects of the intervention on major AEs.

National and Specialty Organizations

American Urological Association (AUA)
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 (AUA Management of BPH/LUTS guidance (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 in a 2020 medical technologies guidance review of Rezūm water vapor therapy for the treatment of BPH.

The guidance notes that 'Evidence supports the case for adopting Rezum for treating LUTS caused by BPH in the NHS. Rezum 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).

SUPPLEMENTAL INFORMATION

International Prostate Symptoms Score (IPSS): IPSS is used to assess the severity of BPH symptoms. The first 7 questions address urinary frequency, nocturia, weak urinary stream, hesitancy, intermittence, incomplete emptying and urgency each on a scale of 0 to 5. The total score, summed across the 7 items measured, ranges from 0 (no symptoms) to 35 (most severe symptoms). A decrease in score indicates improvement

CODING & BILLING INFORMATION

CPT Code

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

HCPCS Codes – N/A

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

12/14/2022 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 (to align with LCD L37808).
   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 (to align with LCD L37808):
   - 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.

REFERENCES

Government Agencies

1. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database (search LUTS, lower urinary tract symptoms, BPH, benign prostatic hyperplasia, Rezūm, or water vapor). Available from CMS.
   - No national coverage determination (NCD) identified (Oct 2022).
   - LCD L37808: Water Vapor Thermal Therapy for LUTS/BPH
2. Food and Drug Administration (FDA).
   - 510k premarket notification: Rezūm System. K150786. September 12, 2016. Available from FDA.
   - Center for Devices and Radiological Health (CDRH). Premarket approval (PMA) database (search: Rezūm System). Available from FDA.

Peer Reviewed Publications

1. Darson MF, Alexander EE, Schiffman ZJ, et al. Procedural techniques and multicenter postmarket experience using minimally invasive convective radiofrequency thermal therapy with Rezūm system for treatment of lower urinary tract symptoms due to benign prostatic hyperplasia. Res Rep Urol. 2017 Aug 21;9:159-168. doi: 10.2147/RRU.S143679. PMID: 28861405; PMCID: PMC5572953.
2. Dixon C, Cedano ER, Pacik D, et al. Efficacy and safety of Rezūm system water vapor treatment for lower urinary tract symptoms secondary to benign prostatic hyperplasia. Urology. 2015;86(5):1042-1047. doi: 10.1016/j.urology.2015.05.046. Epub 2015 Jul 26. PMID: 26216644.
3. Dixon CM, Cedano ER, Pacik D, et al. Two-year results after convective radiofrequency water vapor thermal therapy of symptomatic benign prostatic hyperplasia. Res Rep Urol. 2016;8:207-216. doi: 10.2147/RRU.S119596. PMID: 27921028; PMCID: PMC5123707.
4. Kang TW, Jung JH, Hwang EC, et al. Convective radiofrequency water vapour thermal therapy for lower urinary tract symptoms in men with benign prostatic hyperplasia. Cochrane Database Syst Rev. 2020 Mar 25;3(3):CD013251. doi: 10.1002/14651858.CD013251.pub2. PMID: 32212174; PMCID: PMC7093307.
5. McVary KT, Gange SN, Gittelman MC, et al. 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. 2016a May;195(5):1529-1538. doi: 10.1016/j.juro.2015.10.181. Epub 2015 Nov 22. PMID: 26614889.
6. McVary KT, Gange SN, Gittelman MC, et al. Erectile and ejaculatory function preserved with convective water vapor energy treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia: randomized controlled study. J Sex Med. 2016b;13(6):924-933. doi: 10.1016/j.jsxm.2016.03.372. Epub 2016 Apr 27. PMID: 27129767.

7. McVary KT, Roehrborn CG. Three-year outcomes of the prospective, randomized controlled rezūm system study: Convective radiofrequency thermal therapy for treatment of lower urinary tract symptoms due to benign prostatic hyperplasia. Urology. 2018 Jan;111:1-9. doi: 10.1016/j.urology.2017.10.023. Epub 2017 Nov 6. PMID: 29122620.
8. McVary KT, Rogers T, Roehrborn CG. Rezum water vapor thermal therapy for lower urinary tract symptoms associated with benign prostatic hyperplasia: 4-year results from randomized controlled study. Urology. Apr 2019; 126: 171-179. PMID 30677455.
9. McVary KT, Gittelman MC, Goldberg KA, et al. Final 5-Year Outcomes of the Multicenter Randomized Sham-Controlled Trial of a Water Vapor Thermal Therapy for Treatment of Moderate to Severe Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia. J Urol. Apr 19 2021: 101097JU0000000000001778. PMID 33872051.
10. Miller, L. E., Chughtai, B., McVary, K., et al. (2020). Water vapor thermal therapy for lower urinary tract symptoms secondary to benign prostatic hyperplasia: Systematic review and meta-analysis. Medicine (Baltimore). 2020 Jul 24;99(30):e21365. doi: 10.1097/MD.0000000000021365. PMID: 32791742; PMCID: PMC7387023.
11. Parsons JK, Dahm P, Köhler TS, Lerner LB, Wilt TJ. Surgical management of lower urinary tract symptoms attributed to benignprostatic hyperplasia: AUA Guideline amendment 2020. J Urol. 2020;204(4):799-804. doi:10.1097/ju.0000000000001298
12. Roehrborn CG, Gange SN, Gittelman MC, et al. Convective thermal therapy: Durable 2-year results of randomized controlled and prospective crossover studies for treatment of lower urinary tract symptoms due to benign prostatic hyperplasia. J Urol. 2017;197(6):1507-1516. doi: 10.1016/j.juro.2016.12.045. Epub 2016 Dec 18. PMID: 27993667.
13. Sun F, Sun X, Shi Q, Zhai Y. Transurethral procedures in the treatment of benign prostatic hyperplasia: A systematic review and meta-analysis of effectiveness and complications. Medicine. 2018;97(51):e13360. doi:10.1097/md.0000000000013360. PMID: 30572440; PMCID: PMC6320039.
14. Zabkowski T, Saracyn M. Drug adherence and drug-related problems in pharmacotherapy for lower urinary tract symptoms related to benign prostatic hyperplasia. J Physiol Pharmacol. 2018 Aug;69(4). doi: 10.26402/jpp.2018.4.14. Epub 2018 Dec 9. PMID: 30552307.

National and Specialty Organizations

1. American Urological Association (AUA)
   - Lerner LB, McVary, KT, Barry MJ et al. Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia: AUA Guideline part I: Initial Work-up and Medical Management. J Urol 2021; 206: 806-817. https://doi.org/10.1097/JU.0000000000002183
   - Lerner LB, McVary, KT, Barry MJ et al: Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia: AUA Guideline Part II: Surgical Evaluation and Treatment. J Urol 2021; Oct 2021; 206(4): 818-826. PMID 34384236
2. Canadian Urological Association (CUA). 2010 update: Guideline on male lower urinary tract symptoms/benign prostatic hyperplasia (MLUTS/BPH). Available from CUA. Updated 2018.
3. National Institute for Health and Care Excellence (NICE). Transurethral water vapor ablation for benign prostatic hyperplasia [IPG 1555]. Published August 2018. Available at NICE.

Evidence Based Reviews and Publications

1. DynaMed. Procedural interventions for benign prostatic hyperplasia (BPH). EBSCO Information Services. Available from DynaMed. Registration and login required.
2. Hayes. Health technology assessment: Rezūm System (Boston Scientific Corp.) for benign prostatic hyperplasia. Available from Hayes. Updated October 18, 2021. Registration and login required.
3. Rezūm™ Delivery Device Kit for BPH. Prescriptive information. Boston Scientific. Available Link. Accessed Oct 2022.
4. UpToDate. Available from UpToDate. Registration and login required.
   - Medical treatment of benign prostatic hyperplasia. Literature review current through: Sep 2022. Topic 6891 Version 71.0.
   - Surgical treatment of benign prostatic hyperplasia. Literature review current through: Sep 2022. Topic 8093 Version 41.0.