Subject: Rezūm System for Benign Prostatic Hyperplasia		Original Effective Date: 12/9/20
Policy Number: MCP-384	Revision Date(s):	
MCPC Approval Date: 12/9/20	Review Date: 1/19/21	

Contents

DISCLAIMER

This Molina clinical policy is intended to facilitate the Utilization Management process. 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 (i.e., 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 Molina clinical policy document and provide the directive for all Medicare members.[1]

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

Rezūm System

The Rezūm System is a minimally invasive, transurethral treatment for benign prostatic hyperplasia that utilizes convective radiofrequency water vapor energy to ablate the hyperplastic tissue. The Rezūm procedure is carried out in an office or ambulatory surgery center. Patients typically receive oral anxiolytic and pain medications, but some patients may receive intravenous conscious sedation or prostate block. The Rezūm System consists of a radiofrequency power generator and a disposable delivery device. 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.

Benign Prostate Hypertrophy

Benign Prostate Hypertrophy (BPH) is an enlargement or growth of the prostate that affects men between the ages of 50 and 70 years of age. The enlarged prostate restricts the urethra and applies pressure on 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 urinary tract symptoms (LUTS), such as obstruction, incomplete emptying, intermittency, weak stream, hesitancy, frequency, urgency, and nocturia. BPH and associated LUTS may result in decreased quality of life (QOL) and depression. Initial treatment for BPH includes pharmacologic therapy; followed by surgical intervention. Current surgical treatment of BPH involves a transurethral resection of the prostate (TURP), an inpatient procedure that requires general or spinal anesthesia and is associated with considerable complications. Less invasive techniques that can be performed as outpatient procedures have been developed in an attempt to reduce associated complications and preserve sexual function.

Food and Drug Administration (FDA)

In August 2015, the Rezūm ® System (NxThera, Inc., Maple Grove, MN) received FDA 510(k) approval. The Rezūm System is classified by the FDA as an endoscopic electrosurgical unit. 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 cm3 and ≤ 80 cm3. The Rezūm System is also indicated for treatment of prostate with hyperplasia of the central zone and/or median lobe. [2]

RECOMMENDATION CLINICAL CRITERIA

The Rezūm System used to relieve symptoms, obstructions, and reduce prostate tissue associated with BPH is considered experimental, investigational and unproven due to insufficient published evidence to assess the safety and/or impact on health outcomes.

CONTINUATION OF THERAPY

N/A

LIMITATIONS

N/A

SUMMARY OF MEDICAL EVIDENCE

There is insufficient published evidence to assess the safety and efficacy of the Rezūm System on health outcomes or management of patients with BPH. A very limited number of randomized controlled sham trials prospective and retrospective pretest-posttest studies have included small patient populations (n=65-197) and moderate follow-ups (3 years). This very-low-quality body of evidence suggests that the Rezūm System may improve the LUTS associated with BPH. The effect may be sustained for up to 3-4 years and is not associated with negative sexual AEs. Substantial uncertainty remains, due to the lack of comparative studies and the limited long-term evidence regarding the durability and safety of this treatment method.

McVary et al., (2019) reported 4 year outcomes of the randomized controlled trial of water vapor thermal therapy for treatment of moderate to severe lower urinary tract symptoms due to benign prostatic hyperplasia. According to this study "188 subjects; 135 men ≥50years old, International Prostate Symptom Score ≥ 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. Lower urinary tract symptoms were significantly improved within ≤3 months after thermal therapy and remained consistently durable (International Prostate Symptom Score 47%, quality of life 43%, Qmax 50%, Benign Prostatic Hyperplasia 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 quality of life 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. (2016a) reported outcomes from a prospective, multicenter, double-blind randomized controlled trial (Rezūm II study) using transurethral prostate convective water vapor thermal energy to treat lower urinary tract symptoms (LUTS) associated with BPH. This FDA-approval study included a total of 197 men aged 50 years or older with an International Prostate Symptom Score (IPSS) of 13 or greater, maximum flow rate of 15 ml per second or less, and prostate size 30-80 cc. According to this study "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 three 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 six month follow-up. There were 129 (95.6% of 135) thermal treatment subjects included in the per protocol analysis at six months and 120 at 12 months. The primary endpoint compared a reduction in IPSS at three months. Thermal therapy and control IPSS was reported as reduced by 11.2 ± 7.6 and 4.3 ± 6.9, respectively. Participants in the Rezūm group had an IPSS reduction of 22 points from baseline at two weeks post-treatment and by 50% or greater at three, six and 12

months. The peak flow rate increased by 6.2 ml per second at three months and was sustained throughout 12 months. Adverse events were reported as mild to moderate and resolved quickly." This study is limited by small sample size and short-term follow-up. After three months the study was unblinded.

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 postprocedure assessments included International Prostate Symptom Score (IPSS), quality of life, 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 three to six months, all patients and moderate LUTS. Post-procedure adverse events 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.

Dixon et al. (2015, 2016) reported the one- and two-year clinical outcomes of thermal therapy using convective radiofrequency water vapor thermal therapy with the Rezūm System. According to this study "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, quality of life (QOL) impact, sexual function, and adverse events (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 three– 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 two year follow-up.

Professional Society Guidelines

American Urological Association (AUA): Water vapor thermal therapy is discussed in the updated 2018 (amended 2019) AUA evidence-based Guideline: Surgical Management of Benign Prostatic Hyperplasia/Lower Urinary Tract Symptoms. The guideline recommendation states:

- "Water vapor thermal therapy may be offered to patients with LUTS attributed to BPH provided prostate volume <80g. (Moderate Recommendation; Evidence Level: Grade C)
- Water vapor thermal therapy may be offered to eligible patients who desire preservation of erectile and ejaculatory function. (Conditional Recommendation; Evidence Level: Grade C)"

CODING INFORMATION: THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

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

HCPCS	Description
	N/A

ICD-10	Description: [For dates of service on or after 10/01/2015]
N40	Benign prostatic hyperplasia

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REVISION/REVIEW HISTORY:

12/9/2020: New Policy. Peer Review: [AMR]: Policy reviewed by a practicing physician Board certified in Urology. 10/5/20