

MEDICAL POLICY	Prostate: Water Vapor Thermotherapy for Benign Prostatic Hyperplasia (All Lines of Business Except Medicare)
Effective Date: 4/1/2021	Medical Policy Number: 246
 4/1/2021	Medical Policy Committee Approved Date: 9/19; 10/2020; 3/2021
Medical Officer	Date

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:

All Lines of Business Except Medicare

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

POLICY CRITERIA

I. Water vapor thermotherapy (i.e. Rezūm System) may be considered **medically necessary and covered** for the treatment of benign prostatic hyperplasia (BPH) when all of the following criteria (A.-E.) are met:

- A. Patient is at least 50 years of age; **and**
- B. Patient has moderate-to-severe chronic lower urinary tract symptoms (defined as an American Urologic Association or International Prostate Symptom Score ≥ 8); **and**
- C. Pharmacologic BPH treatment has been unsuccessful or intolerable; **and**
- D. Prostate volume is at least 30 cm³; **and**

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E. Prostate volume is no greater than 80 cm³.

II. Water vapor thermotherapy (i.e., Rezūm System) is considered **investigational and not covered** when criterion I. above is not met.

Link to [Policy Summary](#)

CPT/HCPCS CODES

All Lines of Business Except Medicare	
Prior Authorization Required	
53854	Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy
Unlisted All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then it will be denied as not covered .	
53899	Unlisted procedure, urinary system

DESCRIPTION

Benign Prostatic Hyperplasia

Benign Prostatic Hyperplasia (BPH) is an enlargement of the prostate gland. The prostate gland sits below the bladder and encircles the urethra (the tube that carries urine out of the body). The prostate naturally grows with age, and as it grows it can begin to compress the urethra and because of this, BPH is very common in aging men. Approximately 50% of all men age 51 to 60 have BPH, and approximately 90% of men over the age of 80 have BPH.¹ Many men with BPH do not have symptoms. Men that do have symptoms usually experience frequent urination, a weak urine stream, and/or leaking urine. These BPH symptoms are commonly referred to as lower urinary tract symptoms (LUTS). The treatment for LUTS usually depends on the severity of symptoms. Men with mild BPH may start with life style changes; while men with moderate-to-severe BPH typically require treatment with medications and possibly surgery.²

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Treatment of Benign Prostatic Hyperplasia

Pharmacologic Therapy

There are two types of medicines used to treat BPH: alpha blockers and alpha-reductase inhibitors. Typically, men who start taking BPH medicine will need to take it forever unless surgical treatment is undertaken.² Alpha blockers may be used to treat LUTS related to BPH by relaxing the muscles of the prostate and bladder neck; thus reducing the pressure on the urethra and more urine flow. Alpha blockers begin to work quickly and are usually recommended as the first-line of treatment for mild-to-moderate BPH symptoms.² Alpha-reductase inhibitors stop the prostate from growing and can even cause it to shrink. This type of medication is recommended for men with larger prostates and can take up to six months for symptom improvement. Common side effects of both BPH medicines include dizziness, loss of libido, and sexual dysfunction. These side effects and the need for life-long BPH medication compliance, lead 30% of men to discontinue their BPH medicine after the first year.³

The Rezum System

According to Hayes:

“The Rezum System [i.e. Rezum] is a minimally invasive, transurethral treatment for BPH that utilizes convective radiofrequency water vapor energy to ablate the hyperplastic tissue. The Rezum System consists of a radiofrequency power generator and a disposable delivery device. The rigid shaft of the delivery device incorporates a standard lens so that the procedure may be performed under cystoscopic visualization. The delivery device also contains a needle, which injects wet thermal energy (i.e., steam) into 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 ... Once the Rezum delivery device is within the prostate, the needle is deployed and a 9-second burst of 103°C water vapor is injected into the prostatic tissue creating a spherical lesion of 1.5 to 2 centimeters (cm). 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. The goal is to create contiguous, overlapping lesions approximately 1 cm apart along the urethra.”⁴

REVIEW OF EVIDENCE

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of the Rezum System (NxThera Inc.) as a treatment for benign prostatic hyperplasia. Below is a summary of the available evidence identified through 2/1/2020.

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Systematic Reviews

- In 2019 (updated in 2020), Hayes conducted an evidence review evaluating the safety and efficacy of the Rezum System for the treatment of benign prostatic hyperplasia (BPH).⁴ Searching the literature through February, Hayes included 8 publications for review. The publications reported data from 4 clinical studies (1 randomized, sham-controlled study, and 3 pretest-post-test studies.) Sample sizes across studies ranged from 65 to 197. Primary outcomes of interest included urinary symptoms, health-related quality of life, sexual function, safety and treatment failure. Results across 4 studies suggested that, compared to the sham group, Rezum patients’ LUTS and quality of life significantly improved from baseline at 3-years’ follow-up (50% vs. 20%; p < 0.0001). Measures of clinically meaningful response ranged from 67% to 85% at 12-month follow-up. No significant effect on sexual function was reported across either Rezum or sham patients. Adverse events and failure rates were also minimal.

Hayes judged the overall quality of evidence to be of “very-low,” concluding that Rezum may relieve lower urinary tract symptoms (LUTS) associated with BPH and improve patients’ health-related quality of life at up to 3 years. Limitations across studies may undermine results’ validity, however. Individual studies suffered from small sample sizes, a lack of comparison groups, a lack of long-term follow-up, and substantial loss to follow-up. Hayes ultimately assigned a “D2” rating (insufficient evidence) for use of Rezum in men with LUTS secondary to BPH. Investigators stated that, in addition to unestablished patient selection criteria, “substantial uncertainty remains regarding [Rezum’s] comparative effectiveness and safety due to a lack of comparative studies, as well as limited long-term evidence regarding the durability and safety.”⁴

- In 2016 (updated 2019), ECRI conducted an evidence review assessing the safety and efficacy of Rezum for the treatment of benign prostatic hyperplasia.⁵ Searching the literature through March 2019, ECRI reviewed the full texts of 1 RCT and 3 pre-post studies reporting outcomes for 522 patients. The RCT included for review is the evaluated below.⁶ The pre-post studies are the same as those evaluated in the Hayes review discussed above.⁴ ECRI concluded that the balance of evidence regarding Rezum’s efficacy is “somewhat favorable,” with statistically and clinically significant improvements in patients’ LUTS and quality of life across all studies. Investigators noted that study limitations may undermine results’ validity, noting the limited quantity of RCTs comparing Rezum to a sham procedure (n =1), and the absence of any RCTs comparing Rezum to any other BPH treatment. Sham procedures and pre-post studies were also vulnerable to placebo effects due to the lack of blinding. In the case of the sham procedure, LUTS may also decrease due to temporary urethral dilation caused by rigid cystoscopy, although the placebo effect is thought to dissipate within 6 months. The reviewed pre-post studies also included patients with prostate volumes smaller or larger than described in the FDA-labeled indication (30 to 80cm³), which may have generated results different from reported findings in the on-label population. ECRI concluded that additional studies comparing Rezum to alternative treatments were necessary (e.g. transurethral resection of the prostate, microwave ablation, prostatic urethral lift) so as to more definitively establish Rezum’s safety and efficacy.

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- In 2020, Miller et al conducted an industry-funded systematic review and meta-analysis of water vapor thermal therapy for lower urinary tract symptoms secondary to benign prostatic hyperplasia.⁷ Five cohorts from 4 studies were reviewed, reviewing data from 514 total. The review found that international prostate symptom score, IPSS quality of life, benign prostatic hyperplasia impact index, and maximum flow rate were all improved from baseline. Surgical 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. These studies, already reviewed in the above Hayes and ECRI reports, and this review suffer from a number of limitations. Only one study was randomized, and only participants receiving water vapor thermal therapy were included in analysis. The other 4 studies were small, had short follow-up and had high heterogeneity. There was no comparator, and no conclusions can be made about the efficacy of water vapor thermal therapy compared to standard of care treatments.

Randomized Controlled Trials

In 2019, McVary and colleagues conducted a manufacturer-funded randomized controlled trial reporting lower urinary tract symptoms (LUTS) associated with BPH in patients receiving Rezum.⁶ In total, 188 patients with International Prostate Symptom Score ≥ 13 , with a maximum flow rate (Qmax) $\leq 15\text{mL/s}$ and prostate volume 30 to 80cc were treated and followed for 4 years. A subset of 53 patients who initially received sham treatment “crossed over” to active treatment after unblinding at 3-months. This group was followed for 3 years. Results indicated significant improvement in both groups’ LUTS and quality of life within 3 months of treatment, sustained throughout 4 years ($p < 0.0001$). Results’ validity may be limited by the investigators’ financial conflicts of interest with Rezum’s manufacturer, the lack of treatment groups receiving an alternative BPH therapy, narrow inclusion criteria (e.g. all patients 50 years old, without history of urinary retention or UTI) and significant loss to follow-up (primary group: 32.8%, n = 44/134; cross-over group 45.3% n = 24/53). Investigators concluded that Rezum can provide effective symptom relief and improve quality of life for patients with BPH.

CLINICAL PRACTICE GUIDELINES

American Urological Association

In 2020, the American Urological Association (AUA) updated an evidence-based clinical practice guideline evaluating surgical management of LUTS attributed to BPH.^{8,9} On the basis of grade “C” evidence (i.e. low-quality), the AUA issued a conditional recommendation for water vapor thermal therapy “with LUTS attributed to BPH provided prostate volume $< 80\text{g}$. Water vapor thermal therapy may be offered to eligible patients who desire preservation of erectile and ejaculatory function.” Rezum is not named specifically in the guideline. Several investigators maintain financial conflicts of interest with device manufacturers, including Rezum’s manufacturer.

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National Institute for Health and Care Excellence (NICE)

In 2018, the NICE stated that current evidence on the safety and efficacy of transurethral water vapour ablation for urinary tract symptoms caused by benign prostatic hyperplasia is adequate to support the use of this procedure.¹⁰

POLICY SUMMARY

Low-quality but consistent evidence supports the use of Rezum for the treatment of benign prostatic hyperplasia. Studies to date have consistently reported positive results and low rates of adverse events. The American Urological Association and the National Institute for Health and Care Excellence both endorse water vapor thermotherapy. Results from the largest RCT conducted to date indicate significant improvements in patients’ LUTS compared to baseline, although validity was limited by likely attrition bias (primary group: 32.8%, n = 44/134; cross-over group 45.3% n = 24/53). While additional, high-quality RCTs with longer term follow-up and broader inclusion criteria are required to better determine patient selection criteria, Rezum appears to be at least as safe and effective as comparable treatment options.

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days’ notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

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REGULATORY STATUS

The Rezum System received 501(k) approval in 2015.¹¹

Indications for Use	Contraindications
The Rezum™ 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 30cm ³ ≤ 80cm ³ . The Rezum System is also indicated for treatment of prostate with hyperplasia of the central zone and/or a median lobe.	The use of the Rezūm System is contraindicated for the following: <ul style="list-style-type: none"> • Patients with a urinary sphincter implant • Patients who have a penile prosthesis

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

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