Transurethral Water Vapor Thermal Therapy for Benign Prostatic Hyperplasia

**Introduction**

Benign prostatic hyperplasia (BPH) is a noncancerous enlargement of the prostate gland that is common in men over age 50. The enlarged prostate gland presses against the urethra, the tube that carries urine from the bladder to the outside of the body. BPH can lead to symptoms, like urinary frequency, urgency, and waking up at night to urinate. BPH is treated with watchful waiting, lifestyle changes, medication, and surgery (transurethral resection of the prostate, or TURP). An alternative treatment for BPH is transurethral water vapor thermal therapy. This is a minimally invasive surgery that uses heated water vapor to remove the prostate tissue that is blocking the urethra. Transurethral water vapor thermal therapy for the treatment of benign prostatic hyperplasia is unproven (investigational). More studies are needed to see if this treatment is as good or better than proven methods of treating BPH.

**Note:** The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
Therapy | Investigational
---|---
Transurethral water vapor thermal therapy | Transurethral water vapor thermal therapy is considered investigational as a treatment of benign prostatic hyperplasia.

### Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>CPT</td>
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<tr>
<td>53854</td>
<td>Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy (Rezum System™) (new code effective 1/1/19)</td>
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</tbody>
</table>

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### Related Information

N/A

### Evidence Review

**Background**

Benign prostatic hyperplasia (BPH) is a common condition in older men, affecting to some degree 40% of men in their 50s, 70% of those between ages 60 and 69, and almost 80% of those ages 70 and older.\(^1\), BPH is a histologic diagnosis defined as an increase in the total number of stromal and glandular epithelial cells within the transition zone of the prostate gland. In some men, BPH results in prostate enlargement which can, in turn, lead to benign prostate obstruction and bladder outlet obstruction, which are often associated with lower urinary tract symptoms including urinary frequency, urgency, irregular flow, weak stream, straining, and waking up at night to urinate. Lower urinary tract symptoms is the most commonly presenting urological complaint and can have a significant impact on the quality of life.\(^1\)
BPH does not necessarily require treatment. The decision on whether to treat BPH is based on an assessment of the impact of symptoms on quality of life along with the potential side effects of treatment. Options for medical treatment include alpha-1-adrenergic antagonists, 5-alpha-reductase inhibitors, anticholinergic agents, and phosphodiesterase-5 inhibitors. Medications may be used as monotherapy or in combination.\textsuperscript{2}

Patients with persistent symptoms despite medical treatment may be considered for surgical treatment. The traditional standard treatment for BPH is transurethral resection of the prostate.

Transurethral water vapor thermal therapy has been investigated as a minimally invasive alternative to transurethral resection of the prostate. The procedure uses radiofrequency-generated water vapor (~103°C) thermal energy to ablate prostate tissue.\textsuperscript{3}

**Summary of Evidence**

For individuals who have BPH who receive transurethral water vapor thermal therapy, the evidence includes one small, short-term sham-controlled RCT with a four-year uncontrolled follow-up phase. The outcomes of interest are symptoms, quality of life, and treatment-related morbidity. At three months, lower urinary tract symptoms 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 four years of follow-up. This 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. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this review are listed in Table 1.

**Table 1. Summary of Key Trials**

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tr>
<td><strong>Ongoing</strong></td>
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<tr>
<td>NCT03605745</td>
<td>Minimally Invasive Prostatic Vapor Ablation</td>
<td>88</td>
<td>Aug 2019</td>
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<tr>
<td>NCT No.</td>
<td>Trial Name</td>
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<tr>
<td>Multicenter, Single Arm Study for the Treatment of BPH in Large Prostates (Rezūm XL)</td>
<td></td>
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<tr>
<td>NCT02940392</td>
<td>RezumFirst in Man Feasibility Study for the Treatment of BPH With the Rezum System</td>
<td>15</td>
<td>Jun 2018 (status unknown)</td>
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<tr>
<td>NCT02943070</td>
<td>NxThera Benign Prostatic Hyperplasia RezumSystem Pilot Study</td>
<td>50</td>
<td>Dec 2018 (status unknown)</td>
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</table>

NCT: National Clinical Trial

**Clinical Input Received from Physician Specialty Societies and Academic Medical Centers**

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

**Practice Guidelines and Position Statements**

*The American Urological Association*

The American Urological Association (2018) issued clinical practice guidelines on benign prostatic hyperplasia (amended 2019) and made the following recommendations for water vapor thermal therapy:

- Water vapor thermal therapy may be offered to patients with lower urinary tract symptoms attributed to benign prostatic hyperplasia provided prostate volume <80 g; however, patients should be counseled regarding efficacy and retreatment rates. (Conditional 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)
The recommendations were based on results of the randomized controlled trial conducted by McVary et al. (2015, 2018), and this body of evidence was considered low strength, leading to a conditional recommendation (Grade C).

**Medicare National Coverage**

There is no national coverage determination.

**Regulatory Status**

In September 2016, the Rezum System™ (NxThera, Inc) was cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process (K150786). The Food and Drug Administration determined that this device was substantially equivalent to existing devices (Medtronic Prostiva devices). Rezum™ is intended to relieve symptoms, obstructions, and reduce prostate tissue associated with benign prostatic hyperplasia. It is indicated for men > 50 years of age with a prostate volume >30cm³ and <80cm³. The Rezum System™ is also indicated for the treatment of prostate with hyperplasia of the central zone and/or a median lobe.

**References**


5. McVary, KK, Rogers, TT, Roehrborn, CC. Rezūm Water Vapor Thermal Therapy for Lower Urinary Tract Symptoms Associated With Benign Prostatic Hyperplasia: 4-Year Results From Randomized Controlled Study. Urology, 2019 Jan 25;126:171-179. PMID 30677455

**History**

<table>
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<th>Date</th>
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<tr>
<td>09/01/19</td>
<td>New policy, approved August 13, 2019. Add to Medicine section. This policy was previously archived, but it is now being reinstated with literature review through April 2019. Transurethral water vapor thermal therapy is considered investigational as a treatment of benign prostatic hyperplasia.</td>
</tr>
</tbody>
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