

## MEDICAL POLICY – 2.01.49

# Transurethral Water Vapor Thermal Therapy and Transurethral Water Jet Ablation (Aquablation) for Benign Prostatic Hyperplasia

BCBSA Ref. Policy: 2.01.49

Effective Date: Aug. 1, 2024

Last Revised: July 22, 2024


Replaces: N/A

## RELATED MEDICAL POLICIES:

8.01.61 Focal Treatments for Prostate Cancer

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## 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). Alternative treatments for BPH are transurethral water vapor thermal therapy and aquablation. Water vapor thermal therapy is a minimally invasive surgery that uses heated water vapor to remove the prostate tissue that is blocking the urethra. Aquablation cuts tissue by using a pressurized jet of fluid delivered to the prostatic urethra. Transurethral water vapor thermal therapy and aquablation for the treatment of benign prostatic hyperplasia are unproven (investigational). More studies are needed to see if these treatments are 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.

## Policy Coverage Criteria

Therapy	Investigational
<b>Transurethral water vapor thermal therapy</b>	<b>Transurethral water vapor thermal therapy is considered investigational as a treatment of benign prostatic hyperplasia.</b>
<b>Transurethral waterjet ablation (aquablation)</b>	<b>Transurethral waterjet ablation (aquablation) is considered investigational as a treatment of benign prostatic hyperplasia.</b>

## Coding

Code	Description
<b>CPT</b>	
0421T	Transurethral waterjet ablation of prostate, including control of post-operative bleeding, including ultrasound guidance, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included when performed)
53854	Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy (Rezum System)
<b>HCPS</b>	
C2596	Probe, image guided, robotic, waterjet ablation

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## Related Information

N/A

## Evidence Review

## Description

Transurethral water vapor thermal therapy and transurethral waterjet ablation (aquablation) have been investigated as minimally invasive alternatives to transurethral resection of the prostate (TURP), considered the traditional standard treatment for benign prostatic hyperplasia (BPH). Transurethral water vapor thermal therapy uses radiofrequency-generated water vapor (~103°C) thermal energy based on the thermodynamic properties of convective versus conductive heat transfer to ablate prostate tissue. Aquablation cuts tissue by using a pressurized jet of fluid delivered to the prostatic urethra.

## 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.<sup>1</sup> 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 (LUTS) including urinary frequency, urgency, irregular flow, weak stream, straining, and waking up at night to urinate. Lower urinary tract symptoms are the most commonly presenting urological complaint and can have a significant impact on the quality of life.

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.<sup>2</sup>

Individuals with persistent symptoms despite medical treatment may be considered for surgical treatment. The traditional standard treatment for BPH is transurethral resection of the prostate. TURP is generally considered the reference standard for comparisons of BPH procedures. Several minimally invasive prostate ablation procedures have also been developed, including transurethral microwave thermotherapy, transurethral needle ablation of the prostate, urethromicroablation phototherapy, and photoselective vaporization of the prostate. The prostatic urethral lift procedure involves the insertion of one or more permanent implants into the prostate, which retracts prostatic tissue and maintains an expanded urethral lumen.

Transurethral water vapor thermal therapy and aquablation have been investigated as minimally invasive alternatives to TURP. Transurethral water vapor thermal therapy uses radiofrequency-generated water vapor (~103°C) thermal energy based on the thermodynamic properties of convective vs conductive heat transfer to ablate prostate tissue.<sup>3</sup> Aquablation cuts tissue by using a pressurized jet of fluid delivered to the prostatic urethra.

## Summary of Evidence

For individuals who have benign prostatic hyperplasia (BPH) and lower urinary tract symptoms (LUTS) who receive transurethral water vapor thermal therapy, the evidence includes a single 3-month, sham-controlled randomized controlled trial (RCT) of 197 individuals with a 5-year uncontrolled follow-up phase and one multicenter, prospective, single-arm study. The outcomes of interest are symptoms, quality of life, and treatment-related morbidity. At three 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. The evidence is limited by the small sample size, lack of blinding of longer-term outcomes, and lack of comparison to alternative treatments such as transurethral resection of the prostate (TURP). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have benign prostatic hyperplasia (BPH) and LUTS who receive aquablation, the evidence includes a single noninferiority RCT of aquablation compared to TURP in 187 individuals with 5 years of follow-up, and several multicenter, prospective, single-arm studies. The outcomes of interest are symptoms, quality of life, and treatment-related morbidity. The primary efficacy endpoint was the difference between groups in the change in International Prostate Symptom Score (IPSS) at 6 months, and the primary safety end point was the development of Clavien-Dindo persistent grade 1, or 2 or higher operative complications at 3 months. At 6 months, mean IPSS decreased from baseline by 16.9 points for aquablation and 15.1 points for TURP (mean difference 1.8 points;  $p < .0001$  for noninferiority and  $p = .1347$  for superiority). The primary safety endpoint rate was lower in the aquablation group compared to the TURP group (26% vs 42%,  $p = .0149$ ). The rate of grade 2 and greater events was similar in the 2 groups (20% for aquablation and 23% for TURP;  $p = .3038$ ). Over 5 years, improvements remained similar between groups with no new safety signals. Confidence in these conclusions is reduced due to imprecision of estimates and a lack of additional supportive trials, especially with regard to comparative adverse events. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.



## Ongoing and Unpublished Clinical Trials

An ongoing trial that might influence this review is listed in [Table 1](#).

**Table 1. Summary of Key Trials**

NCT No.	Trial Name	Planned Enrollment	Completion Date
<b>Ongoing</b>			
<a href="#">NCT04838769<sup>a</sup></a>	Water Vapor Thermotherapy vs. Combination Pharmacotherapy for Symptomatic Benign Prostatic Hyperplasia Refractory to Alpha Blocker Monotherapy in Sexually Active Men: A Multicenter Randomized Controlled Trial	394	Jul 2026
<a href="#">NCT05762198</a>	A Randomized Controlled Trial Comparing Water Vapour Thermal Therapy (Rezūm) and TURP in Men With Benign Prostatic Hyperplasia in Refractory Urinary Retention	108	Jun 2026
<a href="#">NCT04338776<sup>a</sup></a>	C.L.E.A.R. - Comparing UroLift Experience Against Rezum	120	May 2025
<a href="#">NCT04801381</a>	WATER III: A Randomized, Controlled Trial of Aquablation vs. Transurethral Laser Enucleation of Large Prostates (80 - 180 mL) in Benign Prostatic Hyperplasia	200	Dec 2028

<sup>a</sup>Denotes industry sponsored or cosponsored trial. NCT: National Clinical Trial

## Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

## The American Urological Association

In 2021, the American Urological Association published guidelines on the surgical evaluation and treatment of lower urinary tract symptoms (LUTS) attributed to benign prostatic hyperplasia (BPH).<sup>19</sup> An amendment to these guidelines was published in 2023.<sup>20</sup> The following recommendations are related to the interventions included in this evidence review:

- Water vapor thermal therapy should be considered as a treatment option for patients with LUTS/BPH provided prostate volume is 30 to 80 cc. (Moderate Recommendation; Evidence Level: Grade C)
- Water vapor thermal therapy 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)

## National Institute for Health and Care Excellence

In 2020, the National Institute for Health and Care Excellence (NICE) issued the following guidance on Rezum for treatment of LUTS secondary to BPH:<sup>21</sup>

- "Evidence supports the case for adopting Rezum for treating lower urinary tract symptoms (LUTS) caused by benign prostatic hyperplasia (BPH) in the NHS. Rezum relieves LUTS and improves quality of life."
- "Rezum is a minimally invasive procedure. It 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<sup>3</sup> and 80 cm<sup>3</sup>)."

In 2023, NICE updated guidance on transurethral water jet ablation for LUTS caused by BPH.<sup>22</sup> The following recommendations were made:

- "Transurethral water-jet ablation for lower urinary tract symptoms caused by BPH may be used if standard arrangements are in place for clinical governance, consent, and audit. For

auditing the outcomes of this procedure, the main efficacy and safety outcomes identified in this guidance can be entered into NICE's interventional procedure outcomes audit tool (for use at local discretion)."

A Medtech innovation briefing was released by NICE in January 2023 but guidance specific to Aquablation is awaiting development.<sup>23</sup>

## Medicare National Coverage

There is no national coverage determination.

## Regulatory Status

In September 2016, the Rezum System (NxThera, Inc., acquired by Boston Scientific in 2018) was cleared for marketing by the US Food and Drug Administration (FDA) through the 510(k) process (K150786). The FDA 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 BPH. It is indicated for men > 50 years of age with a prostate volume >30cm<sup>3</sup> and <80cm<sup>3</sup>. The Rezum System is also indicated for the treatment of prostate with hyperplasia of the central zone and/or a median lobe.

In April 2017, the Aquabeam System (Procept Robotics Corporation) was cleared for marketing by the FDA through the 513(f)(2) (de novo) classification process (DEN170024).<sup>4</sup> The device is intended for the resection and removal of prostate tissue in males with LUTS due to BPH, based on WATER trial.

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## History

Date	Comments
09/01/19	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.
09/01/20	Annual Review, approved August 4, 2020. Policy updated with literature review through May, 2020; references added. Policy statement unchanged.
09/01/21	Annual Review, approved August 10, 2021. Policy updated with literature review through May 13, 2021; references added. New indication and investigational policy statement added for aquablation. Title changed to include Transurethral Water Jet Ablation (Aquablation). Added CPT code 0421T and HCPC code C2596.
09/01/22	Annual Review, approved August 8, 2022. Policy updated with literature review through April 21, 2022; references added. Policy statements unchanged.
09/01/23	Annual Review, approved August 7, 2023. Policy updated with literature review through May 1, 2023; references added. Policy statements unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
08/01/24	Annual Review, approved July 22, 2024. Policy updated with literature review through April 17, 2024; references added. Policy statements unchanged.

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