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MEDICAL POLICY – 2.01.544

Transurethral Water Vapor Thermal Therapy and Transurethral Water Jet Ablation for Benign Prostatic Hyperplasia

BCBSA Ref. Policy:	2.01.49
Effective Date:	Sep. 1, 2025
Last Revised:	Aug. 12, 2025
Replaces:	N/A

RELATED MEDICAL POLICIES:

8.01.61 Focal Treatments for Prostate Cancer

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

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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	Medical Necessity

Transurethral water vapor thermal therapy (e.g. Rezum)	**Transurethral water vapor thermal therapy (e.g., Rezum) is considered medically necessary in individuals with moderate-to-severe lower urinary tract obstruction due to benign prostatic hyperplasia when ALL of the following criteria are met:**
	• International Prostate Symptom Score (IPSS) of 12 or higher; (See **Related Information**)
	AND
	• Failure or inability to tolerate maximally titrated medical therapy (α1-adrenergic antagonists, 5α-reductase inhibitors, or combination medication therapy) over a trial period of no less than 3 months; (See **Related Information**)
	AND
	• Imaging shows prostate gland volume is greater than 30 ml and less than or equal to 80 mL;
	AND
	• The individual does not have any of the following:
	  ○ Urinary tract infection being actively treated; **OR**
	  ○ Prostatitis being actively treated; **OR**
	  ○ Known or suspected prostate cancer;
	
	Transurethral water vapor thermal therapy is considered not medically necessary as a treatment of benign prostatic hyperplasia for individuals not meeting the above criteria.
	
	Transurethral water vapor thermal therapy is considered investigational for the treatment of any condition other than benign prostatic hyperplasia
	
	Repeat treatments using transurethral water vapor thermal therapy are considered investigational.

Transurethral waterjet ablation (e.g. Aquablation)	**Transurethral waterjet ablation (e.g., Aquablation) is considered medically necessary in individuals with moderate-**

Therapy	Medical Necessity

	to-severe lower urinary tract obstruction due to benign prostatic hyperplasia when ALL of the following criteria are met:
	• International Prostate Symptom Score (IPSS) of 12 or higher; (See **Related Information**)
	AND
	• Failure or inability to tolerate maximally titrated medical therapy (α1-adrenergic antagonists, 5α-reductase inhibitors, or combination medication therapy) over a trial period of no less than 3 months; (See **Related Information**)
	AND
	• Imaging shows prostate gland volume is greater than 30 ml and less than or equal to 80 mL
	AND
	• The individual does not have any of the following:
	  ○ Active treatment for urinary tract infection; **OR**
	  ○ Active treatment for prostatitis; **OR**
	  ○ Known or suspected prostate cancer
	
	Transurethral waterjet ablation is considered not medically necessary as a treatment of benign prostatic hyperplasia for individuals not meeting the above criteria.
	
	Transurethral waterjet ablation is considered investigational for the treatment of any condition other than benign prostatic hyperplasia.
	
	Repeat treatments of transurethral waterjet ablation are considered investigational.

Documentation Requirements
The patient's medical records submitted for review for all conditions should document that medical necessity criteria are met, state which procedure is requested, and include the following: • Office visit notes that contain the relevant history and physical **AND**

Documentation Requirements

- International Prostate Symptom Score (IPSS) of 12 or higher
- Failure or inability to tolerate maximally titrated medical therapy (α1-adrenergic antagonists, 5α-reductase inhibitors, or combination medication therapy) over a trial period of no less than 3 months
- Imaging shows prostate gland volume is greater than 30 ml and less than or equal to 80 mL
- The individual does not have any of the following:
  - Active treatment for urinary tract infection; **OR**
  - Active treatment for prostatitis; **OR**
  - Known or suspected prostate cancer

Coding

Code	Description
CPT	
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)
HCPS	
C2596	Probe, image guided, robotic, waterjet ablation

Related Information

The International Prostate Symptom Score (IPSS) is a standardized measure used to assess the severity of lower urinary tract symptoms. It was adopted by the World Health Organization in 1993 and is a validated, reproducible scoring system to assess disease severity and response to

therapy. It is a modification of the American Urological Association (AUA) Symptom Index. The questionnaire assesses degree of lower urinary tract symptoms and quality of life. A score of 7 or less is mildly symptomatic, 8-19 is moderately symptomatic, and 20 to 35 is severely symptomatic. Both the AUA index and the IPSS questionnaire are sensitive enough to be used in evaluating symptoms and selecting treatment. IPSS > 12 [13] was used for inclusion criteria in clinical trials for Aquabeam and Rezum.

Medications used to treat BPH:

α1-adrenergic antagonists (e.g. tamsulosin, silodosin, alfuzosin, doxazosin, terazosin)

5α-reductase inhibitors (e.g. finasteride, dutasteride)

Combination drugs (e.g. dutasteride/tamsulosin)

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.[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 (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.[2]

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.[3] 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 trial 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). Nonrandomized studies comparing transurethral water vapor thermal therapy with prostatic urethral lift have generally found the need for more reintervention with prostatic urethral lift but more complications with transurethral water vapor thermal therapy.

However, the evidence is sufficient to determine that the technology results in an improvement in the net health outcome for properly selected patients.

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. However, the evidence is insufficient to determine that the technology results in an improvement in the net health outcome for properly selected patients.

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
Ongoing			
NCT04838769[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	154	Mar 2027
NCT05762198	A Randomized Controlled Trial Comparing Water Vapour Thermal Therapy (Rezūm) and	108	Jun 2026

NCT No.	Trial Name	Planned Enrollment	Completion Date
	TURP in Men With Benign Prostatic Hyperplasia in Refractory Urinary Retention		
NCT04338776[a]	C.L.E.A.R. - Comparing UroLift Experience Against Rezum	120	Dec 2025
NCT04801381	WATER III: A Randomized, Controlled Trial of Aquablation vs. Transurethral Laser Enucleation of Large Prostates (80 - 180 mL) in Benign Prostatic Hyperplasia	200 (actual)	Oct 2029
NCT06769997	The Optizum Study: A Randomized, Blinded Single Center Study Evaluating the Optilume BPH Catheter System and the Rezum Water Vapor Therapy for the Treatment of Benign Prostatic Hyperplasia	100	Jan 2027

[a]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). [23] An amendment to these guidelines was published in 2023.[24] 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:[25]

- "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^3 and 80 cm^3)."

In 2023, NICE updated guidance on transurethral water jet ablation for LUTS caused by BPH.[26] 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.[27]

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 at least 50 years of age with a prostate volume between 30cm^3 and 80cm^3. 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).[4] 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.
09/01/25	New policy (2.01.544), approved August 12, 2025. Policy replaces 2.01.49 Transurethral Water Vapor Thermal Therapy and Transurethral Water Jet Ablation (Aquablation) for Benign Prostatic Hyperplasia. Policy updated with literature review through April 29, 2025; references added. Policy statements changed to include medically necessary criteria for water vapor thermal therapy and water jet ablation.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.