2.01.49	Transurethral Water Vapor Thermal Therapy and Transurethral Water Jet Ablation (Aquablation) for Benign Prostatic Hyperplasia		
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Section:	7.0 Surgery	**Page:**	Page 1 of 21

Policy Statement

I. Transurethral water vapor thermal therapy is considered **investigational** as a treatment of benign prostatic hyperplasia.

II. Transurethral waterjet ablation (aquablation) is considered **investigational** as a treatment of benign prostatic hyperplasia.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Coding

See the Codes table for details.

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.

Summary of Evidence

For individuals who have benign prostatic hypertrophy (BPH) and lower urinary tract symptoms (LUTS) who receive transurethral water vapor thermal therapy, the evidence includes a single 3-month, sham-controlled, randomized trial of 197 patients with a 5-year uncontrolled follow-up phase and 1 multicenter, prospective, single-arm study. The outcomes of interest are symptoms, functional outcomes, quality of life, and treatment-related morbidity. At 3 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. Additional observational evidence reports favorable short-term safety for transurethral water vapor thermal therapy compared with transurethral resection of the prostate and lower 5-year rates of clinical progression and invasive re-treatment compared with medical therapy. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have BPH and LUTS who receive Aquablation, the evidence includes a single noninferiority randomized controlled trial (RCT) of Aquablation compared to TURP in 181 patients with 5 years of follow-up, and several multicenter, prospective, single-arm studies. The outcomes of interest are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The primary efficacy endpoint in the RCT was the difference between groups in the change in International Prostate Symptom Score (IPSS) at 6 months, and the primary safety endpoint 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.

Additional Information
Not applicable.

Related Policies

- N/A

Benefit Application

Benefit determinations should be based in all cases on the applicable member health services contract language. To the extent there are conflicts between this Medical Policy and the member health services contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal law may prohibit health plans from denying FDA-approved Healthcare Services as investigational or experimental. In these instances, Blue Shield of California may be obligated to determine if these FDA-approved Healthcare Services are Medically Necessary.

Regulatory Status

In September 2016, the Rezum™ System (NxThera, Inc, acquired by Boston Scientific in 2018) was cleared for marketing by the U.S. 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 30 cm^3 and 80 cm^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.

Rationale

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 years and older.[1,] Benign prostatic hyperplasia 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 quality of life.

Benign prostatic hyperplasia 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,]

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 (TURP). Transurethral resection of the prostate 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 1 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 versus conductive heat transfer to ablate prostate tissue.[3,] Aquablation cuts tissue by using a pressurized jet of fluid delivered to the prostatic urethra.

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Transurethral Water Vapor Thermal Therapy

Clinical Context and Therapy Purpose

The purpose of transurethral water vapor thermal therapy in individuals who have benign prostatic hyperplasia (BPH) and lower urinary tract symptoms (LUTS) is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with BPH and LUTS. Symptoms include urinary frequency, urgency, irregular flow, weak stream, straining, and getting up at night to urinate.

Interventions

The therapy being considered is transurethral water vapor thermal therapy. This procedure involves the transurethral injection of steam into the prostate. Once injected, the steam condenses to water, imparting convective energy to the tissue, causing cell death and damage. The technology uses radiofrequency to boil the water to create the steam that is injected but does not impart radiofrequency directly to the prostate tissue. Individuals typically require catheterization for at least 1 week due to post-procedure sloughing of prostatic tissue.

Medical management of pain and anxiety may also be required. In one RCT, 69% of participants received oral sedation only, 21% received a prostate block, and 10% received intravenous sedation.

Comparators

The following practices and therapies are currently being used to make decisions about transurethral water vapor thermal therapy:

- Conservative treatment, including watchful waiting and lifestyle modifications;
- Pharmacotherapy;
- Transurethral resection of the prostate (TURP);
- Prostatic urethral lift.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, quality of life, retreatment rates, and treatment-related morbidity.

The International Prostate Symptom Score (IPSS) is used to assess the severity of BPH symptoms. The first 7 questions address urinary frequency, nocturia, weak urinary stream, hesitancy, intermittence, incomplete emptying, and urgency each on a scale of 0 to 5. The total score, summed across the 7 items measured, ranges from 0 (no symptoms) to 35 (most severe symptoms). A decrease in score indicates improvement.

Quality of life (QoL) is assessed with various scales including the IPSS-QoL.

Erectile and ejaculatory function is assessed in sexually active individuals only. Scales include the International Index of Erectile Function and the Male Sexual Health Questionnaire.
Both short-term (up to 12 months) and long-term (12 months and longer) outcomes should be assessed. Treatment-related morbidity can also be assessed in the immediate post-procedure period.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;

- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

Review of Evidence

Systematic Review

Kang et al (2020) conducted a Cochrane review of transurethral water vapor thermal therapy for management of LUTS in men with BPH.[5] In literature searches conducted through February 2020, the reviewers identified only a single RCT (McVary et al [2015],[6] discussed in the section below). The reviewers concluded that there was moderate-to low-certainty evidence that the procedure appears to improve urologic symptom scores and QoL compared to a sham procedure. However, there was very low certainty of evidence about the effects of the intervention on major adverse events.
In a network meta-analysis of reintervention rates for new surgical interventions for BPH, Shin et al (2024) identified 10 RCTs and 22 prospective cohort studies in 2400 patients.[7] Transurethral resection of the prostate was the best-ranked treatment at 12 months followed by transurethral water jet ablation (Aquablation), temporary implantable nitinol device (iTIND), transurethral water vapor thermal therapy, and prostatic urethral lift. Reintervention rates for transurethral water vapor thermal therapy were 0.02% which was similar to TURP at 0.02%.

Randomized Controlled Trial

Transurethral water vapor thermal therapy (Rezum) has been evaluated in a single RCT conducted in 197 men (Table 1). Three-month results were reported in McVary et al (2015).[6] The trial also had an uncontrolled, open-label, crossover phase. After unblinding at 3 months, control subjects who elected to proceed were requalified for the crossover study. A total of 97 patients were followed through 3 years and 90 patients through 4 years. Three-year results were reported in McVary et al (2018)[3], and 4-year results in McVary et al (2019).[8] These results are shown in Table 1.

A second RCT (N=100) comparing transurethral water vapor thermal therapy with bipolar TURP was published by Samir et al (2024), but included men with prostate volumes up to 120 cm^3 which exceeds the current FDA approval limit of 80 cm^3.[9] Thus, further discussion of this RCT is not included in this review of evidence.

Table 1. Randomized Controlled Trial of Rezum: Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	*Comparator*
McVary et al 2015,[6] 2018[3], 2019[8], 2021[10] NCT01912339	United States	15	2013-2016	Men with moderate to severe symptomatic BPH, at least 50 years of age (61% were under age 65 years) with IPSS ≥13, a prostate volume of 30 mL to 80 mL, Qmax of ≤15 mL/s, and a measured postvoid residual urine of <250 mL. Exclusion criteria included a prostate-specific antigen >2.5 ng/mL with a free prostate specific antigen <25% (unless prostate cancer was ruled out by biopsy) and an active urinary tract infection.	n=136 Transurethral water vapor thermal therapy (Rezum)	n=61 Sham procedure with rigid cystoscopy and activation of the system generator outside the subject's body to mimic the sound of the active procedure

BPH: benign prostatic hyperplasia; IPSS: International Prostate Symptom Score; NCT: national clinical trial; Qmax: maximum urinary flow rate.

Results of the RCT are shown in Table 2. The primary outcome was the difference in the change from baseline between the treatment and control arms at 3 months post-treatment. The secondary outcome was the percentage of responders at 3 months. Response was defined as a 30% or greater improvement (reduction) in the IPSS at 3 months compared to baseline. The Rezum group showed an 11.2-point decrease in IPSS, versus a 4.3-point decrease in the sham group (p<.001). There were more responders (defined as 30% or more improvement in the IPSS) in the Rezum group. Notably, more than half of the patients in the control group were classified as responders at 3 months. There were significant differences in other measures of LUTS and QoL.

One hundred thirty of the 197 participants (70.0%) reported being sexually active at baseline and were assessed for erectile function. There were no significant changes in erectile or ejaculatory function at follow-up and no differences between groups. That is, the treatment was not associated with adverse effects on erectile or ejaculatory function. A *post hoc* subgroup analysis of 125 Rezum-treated subjects who were sexually active at baseline found that sexual function continued to be unimpacted at 5 years.[11,] However, only 67 of these participants (53.6%) had follow-up data at this timepoint.

Two patients in the Rezum group experienced 3 serious procedure-related adverse events: 1 patient had de novo extended urinary retention and another had nausea and vomiting due to alprazolam and was hospitalized overnight for observation.

Table 2. Randomized Controlled Trial of Rezum: Results

Study	IPSS change from baseline	Responders (30% improvement in IPSS)	IPSS QoL	Qmax (mL/s)	BPHII	IIEF-EF	MSHQ-EjD function	MSHQ-EjD bother	Serious AEs
McVary et al (2015)[6,]									
N analyzed	197	197	197	194	195	130	130	130	197
Rezum	-11.2 (7.6)	106/136 (77.9%)	-2.1 (1.6)	6.2 (7.1)	-3.4 (3.5)	0.1 (7.4)	0.3 (4.3)	-0.4 (1.9)	66/136 (48.5%)
Sham	-4.3 (6.9)	21/61 (59.5%)	-0.9 (1.5)	0.5 (4.2)	-1.5 (3.0)	-1.5 (3.0)	-0.2 (3.2)	-0.2 (1.9)	4/61 (6.6%)
p-value	<.0001	<.0001	<.0001	<.0001	<.0003	.0003	.443	.623	NR

AE: adverse events; BPHII: benign prostatic hyperplasia Impact Index; IIEF: International Index of Erectile Function; IPSS: International Prostate Symptom Score; MSHQ-EjD: Male Sexual Health Questionnaire for Ejaculatory Dysfunction; NR: not reported; Qmax: peak urinary flow rate; QoL: quality of life.
The trial also had an uncontrolled, open-label, crossover phase, reported in McVary et al (2018), McVary et al (2019), and McVary et al (2021). After unblinding at 3 months, control subjects who elected to proceed were requalified for the crossover study. A total of 98 patients were followed through 60 months. These results are shown in Table 3. Urinary symptoms and QoL remained significantly improved from baseline up to 5 years. Over 5 years, the surgical retreatment rate was 4.4% and the medication retreatment rate was 11.1%.[10,]

Table 3. Randomized Controlled Trial of Rezum: Results of Open-label Uncontrolled Crossover Phase (McVary et al [2018][3,], McVary et al [2019][8,], and McVary et al [2021])[10,]

Outcome, mean change from baseline (SD)	3 months	6 months	12 months	24 months	36 months	48 months	60 months[1]
IPSS							
N	134	129	121	109	97	90	
Change	-11.3 (7.6)	-12.2 (7.6)	-11.6 (7.3)	-11.2 (7.3)	-11.0 (7.1)	-10.1 (7.6)	-11.1 (7.8)
p-value	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001	
IPSS QoL							
N	134	129	121	109	97	90	

Outcome, mean change from baseline (SD)	3 months	6 months	12 months	24 months	36 months	48 months	60 months[1]
Change	-2.1 (1.6)	-2.3 (1.6)	-2.2 (1.6)	-2.2 (1.5)	-2.2 (1.6)	-2.0 (1.7)	-2.2 (1.4)
p-value	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001	
Qmax							
N	125	119	112	99	80	81	
Change	6.4 (7.2)	5.7 (6.2)	5.5 (6.4)	4.8 (6.1)	3.5 (4.7)	4.2 (5.7)	4.1
p-value							
PVR volume							
N	133	125	118	106	92	89	
Change	-10.6 (68.3)	-8.4 (75.8)	-3.9 (82.7)	-0.3 (85.3)	-26.4 (63.9)	-9.2 (72.2)	NR
p-value	.3459	.3721	.8943	.6549	.0004		
BPHII							
N	143	129	121	109	97	90	
Change	-3.4 (3.5)	-4.1 (3.0)	-3.9 (3.3)	-3.8 (3.1)	-3.7 (3.3)	-3.5 (3.4)	-2.2 (1.4)
p -value	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001	
IIEF-EF							
N	90	84	77	71	62	58	
Change	0.1 (7.4)	-0.3 (6.4)	-0.3 (7.5)	-1.2 (7.6)	-1.9 (8.2)	-2.5 (8.7)	-2.4 ± 9.2
p-value	.8927	.8816	.8709	.4080	.1119	.03333	
MSHQ-EjD Function							
N	90	83	78	70	63	56	
change	0.3 (4.3)	0.1 (3.6)	-0.3 (3.5)	-0.5 (4.2)	-1.4 (3.8)	-1.8 (4.4)	NR
p-value	.5612	.7451	.2778	.3505	.0033	.0038	
MSHQ-EjD Bother							
N	90	84	79	70	63	56	
change	-0.3 (1.9)	-0.4 (1.9)	-0.7 (1.8)	-0.5 (1.7)	-0.5 (1.6)	-0.1 (1.8)	NR
p-value	.776	.951	.0015	.0129	.0060	.6495	

[1]Some outcomes were presented graphically only and did not include number analyzed, P-values, or change from baseline.
BPHII: Benign Prostatic Hyperplasia Impact Index; IIEF-EF: International Index of Erectile Function; IPSS: International Prostate Symptom Score; MSHQ-EjD: Male Sexual Health Questionnaire for Ejaculatory Dysfunction; NR: not reported; PVR: postvoid residual urine volume; Qmax: peak urinary flow rate; QoL: quality of life; SD: standard deviation.

Notable relevance and study design and conduct limitations of the RCT reported by McVary et al are summarized in Tables 4 and 5. The major limitations were the short follow-up duration in the sham-controlled phase, and lack of blinding, no control group, and high loss to follow-up in the follow-up phase. Additionally, no studies have compared Rezum to medical management, TURP, or other minimally invasive procedures. Because LUTS in men with BPH may improve spontaneously over time, it is important for future studies to include a longer follow-up period with a control group.

Table 4. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
McVary et al (2015)[6],			Sham procedure; no comparison to alternative treatments	Clinically significant difference on symptoms not prespecified	1, 2: 3 months
McVary et al (2018)[3], McVary et al (2019)[8], and McVary et al (2021)[10],			No control group (comparison to baseline only)	Clinically significant difference in symptom outcomes not prespecified	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 5. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
McVary et al (2015)[6,]						
McVary et al (2018)[3,], McVary et al (2019)[8,], and McVary et al (2021)[10,]		1, 2, 3: open label		High loss to follow-up (97/197 [49%] had 3-year data on primary outcome), 90/197 (46%) had 4-year data), 98/197 (50%) had 5-year data		

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Nonrandomized Studies

Law et al (2024) prospectively compared transurethral water vapor thermal therapy with prostatic urethral lift in 148 patients with BPH from a single institution.[12,] The intervention was determined by patient choice. Tables 6 and 7 describe the study characteristics and results, respectively. There was little difference in clinical outcomes between treatments with the exception of more reoperations with prostatic urethral lift; however, patients undergoing transurethral water vapor thermal therapy had more complications including urinary tract infections and hematuria.

Lim et al (2025) utilized electronic health records to retrospectively compare transurethral water vapor thermal therapy with prostatic urethral lift in patients with BPH.[13,] Tables 6 and 7 describe the study characteristics and results, respectively. Similar to Law et al (2024) there were more reinterventions with prostatic urethral lift and more complications with transurethral water vapor thermal therapy.

Table 6. Summary of Key Nonrandomized Trial Characteristics

Study	Study Type	Country	Dates	Participants	Treatment 1	Treatment 2	Follow-Up
Law et al (2024)[12,]	Prospective cohort	Singapore	2019-2022	148 patients with BPH choosing minimally invasive surgery and prostate volumes ≤80 mL who did not tolerate or prefer medical therapy	Transurethral water vapor thermal therapy (n=86)	Prostatic urethral lift (n=62)	2 years
Lim et al (2025)[13,]	Retrospective cohort	NR	2014-2024	6640 adult males with BPH	Transurethral water vapor thermal therapy (n=3320)	Prostatic urethral lift (n=3320)	Up to 5 years

BPH: benign prostatic hyperplasia; NR: not reported.

Table 7. Summary of Key Nonrandomized Trial Results

Study	Need for reoperation	Need for BPH medication restart	Need for reoperation or BPH medication restart	Complications
Law et al (2024)[12,]	N=148	N=148	N=148	N=148
Transurethral water vapor thermal therapy, n (%)	0	15 (17.4%)	15 (17.4%)	36 (41.9%)
Prostatic urethral lift, n (%)	5 (8.1%)	13 (22.6%)	18 (29.0%)	10 (16.1%)
Effect size (95% CI; p-value)	NR (NR;.01)	NR (NR;.553)	NR (NR;.137)	NR (NR; <.001)
	Hematuria	**UTI**	**Reintervention at 5 years**	
Lim et al (2025)[13,]	N=6640	N=6640	N=6640	
Transurethral water vapor thermal therapy, n (%)	230 (6.9)	246 (7.4)	226 (6.81)	
Prostatic urethral lift, n (%)	171 (5.2)	129 (3.9)	260 (10.85)	
HR (95% CI; p-value)	1.33 (1.09 to 1.67;.0049)	1.91(1.55 to 2.37; <.0001)	0.74 (0.62 to 0.87;.0003)	

BPH: benign prostatic hyperplasia; CI: confidence interval; HR: hazard ratio; NR: not reported; UTI: urinary tract infection.

Additional real-world evidence is available from 2 recent observational studies that compared transurethral water vapor thermal therapy to other comparators.

Page et al (2025) reported real-world outcomes from a national-level retrospective analysis of 155,874 adults undergoing first surgical intervention for benign prostate enlargement across 129 National Health Service hospitals in England between April 2012 and October 2022 using Hospital Episode Statistics. [14,] Among the 1,145 individuals receiving transurethral water vapor thermal therapy and the 114,816 receiving transurethral resection of the prostate, which served as the reference modality for all multivariable comparisons, in-hospital complication rates were 0.7% (95% CI, 0.2 to 1.2) versus 5.9% (95% CI, 5.8 to 6.1) and 30-day emergency re-admission rates were 9.4% (95% CI, 7.7 to 11.1) versus 12.3% (95% CI, 12.1 to 12.4), respectively. The multivariable Cox proportional hazards

model reported a hazard ratio for re-intervention of 1.07 (95% CI, 0.44 to 2.63) for transurethral water vapor thermal therapy compared with transurethral resection of the prostate, however, follow-up for the transurethral water vapor thermal therapy cohort was limited (median 263 days), which precluded estimation of a 5-year re-intervention probability for this modality. Limitations include, but are not limited to, outcomes were limited to Hospital Episode Statistics, analysis did not perform a direct head-to-head comparison of transurethral water vapor thermal therapy with prostatic urethral lift, follow-up duration in the transurethral water vapor thermal therapy cohort was insufficient to assess long-term durability, and data derived from a single-country (England) administrative dataset that may not generalize to U.S. clinical practice.

Long et al (2025) reported 5-year outcomes from a propensity-weighted analysis comparing transurethral water vapor thermal therapy with medical therapy for lower urinary tract symptoms secondary to benign prostatic hyperplasia from data generated by 2 separate clinical trials. [15,] The analysis combined the transurethral water vapor thermal therapy treatment arm of a sham-controlled randomized trial (n=130 of 136 randomized; NCT01912339, enrolled 2013–2014) with the placebo (n=331), doxazosin (n=370), finasteride (n=391), and combination-therapy (n=385) arms of the Medical Therapy of Prostatic Symptoms (MTOPS) trial (NCT00021814, enrolled 1995–1998), restricted to participants meeting Rezum inclusion criteria of prostate volume 30 to 80 cc and International Prostate Symptom Score (IPSS) ≥13. Inverse probability weighting was applied to balance baseline characteristics between cohorts. At 5 years, transurethral water vapor thermal therapy was associated with the lowest rate of overall clinical progression at 4.6%, compared to 19.3% for placebo (p<.001), 11.4% for doxazosin (p=.003), 11.5% for finasteride (p=.002), and 7.5% for combination therapy (p=.12). Mean reduction in IPSS from baseline favored transurethral water vapor thermal therapy initially across all comparisons, however, by year 5 the advantage was statistically significant only against placebo (△=2.6; 95% CI, 0.2 to 4.9; p=.035) and doxazosin (△=2.7; 95% CI, 0.8 to 4.6; p=.004). Limitations include, but are not limited to, the retrospective observational design, the 2 cohorts enrolled individuals across substantially different time periods with consequent differences in standard of care, diagnostic practices, and patient demographics that are not reflective of the current clinical setting, and the loss of approximately 38% of the transurethral water vapor thermal therapy cohort prior to 5-year follow-up.

Section Summary: Transurethral Water Vapor Thermal Therapy

Transurethral water vapor thermal therapy (Rezum) effectively reduced symptoms of BPH compared to sham treatment in one RCT with 5 years of follow-up; however, randomized comparisons to TURP or other active therapies are lacking. 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. Additionally, observational evidence reports favorable short-term safety for transurethral water vapor thermal therapy compared with transurethral resection of the prostate and lower 5-year rates of clinical progression and invasive re-treatment compared with medical therapy.

Transurethral Waterjet Ablation (Aquablation)

Clinical Context and Therapy Purpose

The purpose of Aquablation in individuals who have BPH and LUTS is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with BPH and LUTS. Symptoms include urinary frequency, urgency, irregular flow, weak stream, straining, and getting up at night to urinate.

Interventions
The therapy being considered is transurethral waterjet ablation, known as Aquablation. Aquablation cuts tissue by using a pressurized jet of fluid delivered to the prostatic urethra. The device is able to image the treatment area, or pairs with an imaging modality, to monitor treatment progress.

Comparators
The following practices and therapies are currently being used to make decisions about Aquablation:

- Conservative treatment, including watchful waiting and lifestyle modifications;
- Pharmacotherapy;
- TURP;
- Prostatic urethral lift.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, quality of life, retreatment rates, and treatment-related morbidity.

The IPSS is used to assess the severity of BPH symptoms. The first 7 questions address urinary frequency, nocturia, weak urinary stream, hesitancy, intermittence, incomplete emptying, and urgency each on a scale of 0 to 5. The total score, summed across the 7 items measured, ranges from 0 (no symptoms) to 35 (most severe symptoms). A decrease in score indicates improvement. Quality of life is assessed with various scales including the IPSS-QoL.

Erectile and ejaculatory function is assessed in sexually active individuals only. Scales include the International Index of Erectile Function and the Male Sexual Health Questionnaire.
Both short-term (up to 12 months) and long-term (12 months and longer) outcomes should be assessed. Treatment-related morbidity can also be assessed in the immediate post-procedure period.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

Review of Evidence

Systematic Review

Elterman et al (2021) performed a meta-analysis of individual patient data from 4 prospective, multicenter trials (N=425) with Aquablation in the management of symptomatic BPH (Tables 8 to 10).[16,] The 4 studies were WATER (an RCT), WATER II (a prospective single-arm study), OPEN WATER (a prospective single-arm study), and FRANCAIS WATER (an observational study). Each study had at least 1 year of follow-up. Pooled results from all 4 studies showed improvement from baseline in IPSS, IPSS-QoL, maximum urine flow rate, and postvoid residual volume. There were no new cases of erectile dysfunction postoperatively, but 10.8% of men reported new ejaculatory dysfunction.
In a network meta-analysis of reintervention rates for new surgical interventions for BPH, Shin et al (2024) identified 10 RCTs and 22 prospective cohort studies in 2400 patients.[7,] Transurethral resection of the prostate was the best-ranked treatment at 12 months followed by transurethral water jet ablation (Aquablation), temporary implantable nitinol device (iTIND), transurethral water vapor thermal therapy, and prostatic urethral lift. Reintervention rates for Aquablation were 0.01% which was similar to TURP at 0.02%. Notably, although the study included 4 trials for Aquablation, only one trial had a comparator group (see WATER in Randomized Controlled Trial).

Table 8. Comparison of Trials/Studies Included in Systematic Review and Meta-Analysis

	Elterman et al (2021)[16,]
Gilling et al (2019)[17,]; WATER	●
Bhojani et al (2019)[18,]; WATER II	●
Misrai et al (2019)[19,]; FRANCAIS WATER	●
Bach et al (2020)[20,]; OPEN WATER	●

Table 9. Systematic Review & Meta-Analysis Characteristics

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Elterman et al (2021)[16,]	2015-2019	4	Men treated with Aquablation for BPH	425 (30 to 178)	1 RCT, 2 uncontrolled cohorts, 1 observational study	At least 1 year

BPH: benign prostatic hyperplasia; RCT: randomized controlled trial.

Table 10. Systematic Review & Meta-Analysis Results

Study	IPSS change from baseline (points)	IPSS-QoL change from baseline (points)	Qmax change from baseline (mL/s)	PVR change from baseline (mean, mL)
Elterman et al (2021)[16,]				
N	425	425	425	425
Pooled effect	-16	-3.3	9.4	-62

IPSS: International Prostate Symptom Score; PVR: postvoid residual urine volume; Qmax: peak urinary flow rate; QoL: quality of life.

Randomized Controlled Trial

Aquablation for treatment of BPH has been assessed in a single RCT, known as WATER (Waterjet Ablation Therapy for Endoscopic Resection of Prostate Tissue).[17,] WATER was a noninferiority trial comparing Aquablation with TURP in 181 participants at 17 sites in 4 countries (Table 11). Participants were men ages 45 to 80 years with moderate-to-severe LUTS, defined as an IPSS 10 score ≥12, and prostate size between 30 and 80 mL. The primary efficacy endpoint was the difference between groups in the change in IPSS at 6 months, and the primary safety endpoint was the development of Clavien-Dindo persistent grade 1, or 2 or higher operative complications at 3 months. Primary endpoint results were reported by Gilling et al in 2018,[17,] 12-month results in Gilling et al (2019),[21,], 3-year results in Gilling et al (2020) [22,], and 5-year results in Gilling et al (2022)[23,] Additionally, a synthesis of the trial results up to 12 months was reported in a Cochrane systematic review conducted by Hwang et al (2019).[24,]

On the primary efficacy outcome in WATER, Aquablation was noninferior to TURP. 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).

Table 11. Summary of Key Randomized Controlled Trial Characteristics

Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	*Comparator*
WATER[17,22,23,] NCT02505919	US, UK, Australia, New Zealand	17	October 2015-December 2016	Men age 45 to 80 years with a prostate size between 30 to 80 mL, moderate-to severe LUTS	Aquablation n=65	TURP n=116

Trial	Countries	Sites	Dates	Participants	Interventions
				(IPSS 10 to ≥12), and Qmax <15 mL/s.	

IPSS: International Prostate Symptom Score; LUTS: lower urinary tract symptoms; Qmax: peak urinary flow rate; TURP: transurethral resection of the prostate; WATER: Waterjet Ablation Therapy for Endoscopic Resection of Prostate Tissue.

WATER trial results at 12 months, as summarized in the Cochrane review, are shown in Table 12. The reviewers assessed the certainty of the evidence for each outcome using the GRADE approach.[24,] The reviewers concluded that up to 12 months, Aquablation likely results in a similar improvement in urologic symptom scores to TURP and may result in similar quality of life when compared to TURP. The authors also concluded that Aquablation may result in little to no difference in major adverse events, but considered the evidence for this finding very low certainty due to study limitations and imprecision of estimates.

Table 12. WATER Trial Results at 12 months (Adapted from Hwang et al [2019][24,])

Outcome at 12 months	N Analyzed	Mean Difference (95% CI)	Certainty of the Evidence (Reason for downgrading)
IPSS	174	-0.6 (-2.51 to 2.39)	Moderate (study limitations)
IPSS QoL	174	0.27 (-0.024 to 0.78)	Low (imprecision)
Major adverse events	181	15 fewer per 1000 (-64 to 116) RR 0.84 (0.31 to 2.26)	Very low (high risk of performance bias, unclear risk of reporting bias, wide CI crosses assumed threshold of minimal clinically important difference)
Retreatment	181	10 more per 1000 (13 fewer to 228 more) RR 1.68 (0.18 to 15.83)	Very low (imprecision and high risk of performance and attrition bias)
Erectile function	64	2.31 (-0.63 to 5.25)	Very low (imprecision and high risk of performance and attrition bias)
Ejaculatory function	121	2.57 (0.6 to 4.53)	Very low (imprecision: CI crosses assumed threshold of minimal clinically important difference, high risk of performance and attrition bias)

Source: adapted from Hwang et al (2019)[24,]
CI: confidence interval; IPSS: International Prostate Symptom Score; QoL: quality of life; RR: relative risk; WATER: Waterjet Ablation Therapy for Endoscopic Resection of Prostate Tissue.

Gilling et al (2020) and Gilling et al (2022) reported WATER trial results at 3 and 5 years, respectively (Table 13).[22,23,] Improvements in symptoms and quality of life were maintained through 3 years in both treatment groups, and the rate of serious adverse events did not differ between groups at any time point. Efficacy was maintained through 5 years as well, but safety results were not reported beyond 3 years.

Table 13. WATER Trial Results at 3 and 5 Years

Study	Mean IPSS reduction	Mean % reduction in IPSS	Improvement at least 5 points from baseline	IPSS QoL improvement	Qmax (mL/s)	Retreatment Rate	Serious AEs Subjects (%)
WATER[22,23,] NCT02505919							
3 year results							

Study	Mean IPSS reduction	Mean % reduction in IPSS	Improvement at least 5 points from baseline	IPSS QoL improvement	Qmax (mL/s)	Retreatment Rate	Serious AEs Subjects (%)
Aquablation	14.4 (6.8)	64%	78%	3.2 (1.8)	11.6	5/116 (4.3%)	0 to 3 months: 7 (6.0%) 3 months to 1 year: 5 (4.3%) 1 to 2 years: 8 (6.9%) 2 to 3 years: 4 (3.4%)
TURP	13.9 (8.6)	61%	82%	3.2 (1.7)	8.2	1/65 (1.5%)	0 to 3 months: 4 (6.2%) 3 months to 1 year: 5 (7.7%) 1 to 2 years: 2 (3.1%) 2 to 3 years: 1 (1.5%)
Difference	0.6 (-3.3 to 2.2)	3%	4%	0	3.3 (-0.5 to 7.1)	2.8%	
p-value	.6848	NS	NS	.7845	.0848	.4219	NS at any time point
5 year results							
Aquablation	15.1 (6.6)	NR	NR	NR	8.7 (9.1)	6.0%	NR
TURP	13.2 (8.2)	NR	NR	NR	6.3 (7.5)	12.3%	NR
Difference	1.9	NR	NR	NR	NR	6.3%	NR
p-value	.2764	NR	NR	NR	NR	NR	NR

AE: adverse events; IPSS: International Prostate Symptom Score; NR: not reported; NS: not significant; Qmax: peak urinary flow rate; QoL: quality of life; TURP: transurethral resection of the prostate; WATER: Waterjet Ablation Therapy for Endoscopic Resection of Prostate Tissue.

Study design and conduct limitations of the WATER trial are displayed in Tables 14 and 15. Limitations included a lack of blinding of treating clinicians and baseline evaluators, but blinding of study participants makes this less of a concern. Adverse events were adjudicated up to 1 year, but not after 1 year.

Table 14. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
WATER[17,22,23,] **NCT02505919**				Adverse events occurring after month 12 were not adjudicated by the clinical events committee	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.

[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 15. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
WATER[17,22,23,] **NCT02505919**		Baseline evaluation and study surgeons were not blinded; patients and outcome assessors were blinded	Unclear - secondary outcomes not prespecified			

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Section Summary: Transurethral Waterjet Ablation (Aquablation)

Aquablation was compared to TURP in the WATER trial, with follow-up until 5 years. Aquablation was superior to TURP for the primary safety endpoint at 6 months, but few safety results beyond 6 months are available. At 3 years and 5 years, there were no significant differences between groups in IPSS scores.

Supplemental Information

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

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' 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.

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). [25,] An amendment to these guidelines was published in 2023.[26,] 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 g. (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 g. (Conditional Recommendation; Evidence Level: Grade C)

In 2026, the American Urological Association published guidelines on the surgical evaluation and treatment of lower urinary tract symptoms (LUTS) attributed to benign prostatic hyperplasia (BPH).[27,] The following recommendations are related to the interventions included in this evidence review:

- Clinicians should offer water vapor thermal therapy as an option for patients with prostates 30-80 cc for the treatment of LUTS/BPH. (Moderate Recommendation; Evidence Level: Grade B)

National Institute for Health and Care Excellence
In 2020, the NICE issued the following guidance on Rezum for treatment of LUTS secondary to BPH:[28,]

"Evidence supports the case for adopting Rezum for treating lower urinary tract symptoms (LUTS) caused by benign prostatic hyperplasia (BPH) in the NHS [National Health Service]. 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.[29,] 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.[30,]

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Ongoing trials that might influence this review are listed in Table 16.

Table 16. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT04838769[a]	• 42095468 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 TURP in Men With Benign Prostatic Hyperplasia in Refractory Urinary Retention	108	Jun 2026
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	202 (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
NCT07159165	Minimal Invasive Urology Society Benign Prostatic Obstruction (BPO) Study Group Data Collection Project	10000	Jul 2035
NCT07377929	Intradetrusor Onabotulinumtoxin A (Botox) at the Time of Transurethral Resection of the Prostate or Transurethral Waterjet Ablation of the Prostate for Mixed Lower Urinary Tract Symptoms	20	May 2027
NCT07416227	Comparison Between Water Vapor Thermal Therapy and Prostatic Artery Embolization in Treatment of Benign Prostatic Hyperplasia	30	Oct 2027

[a]Denotes industry sponsored or cosponsored trial
NCT: National Clinical Trial

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Documentation for Clinical Review

- No records required

Coding

The list of codes in this Medical Policy is intended as a general reference and may not cover all codes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy.

Type	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
	0582T	Transurethral ablation of malignant prostate tissue by high-energy water vapor thermotherapy, including intraoperative imaging and needle guidance
	53854	Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy
	55899	Unlisted procedure, male genital system
	52597	Transurethral robotic-assisted waterjet resection of prostate, including intraoperative planning, ultrasound guidance, control of postoperative bleeding, complete, including vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy, when performed ***(Code effective 1/1/2026)***
HCPCS	C2596	Probe, image guided, robotic, waterjet ablation

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
08/01/2019	BCBSA Medical Policy adoption
03/01/2020	Coding update
08/01/2023	Policy reactivated. Previously archived from 07/01/2020 to 07/31/2023.
08/01/2024	Annual review. No change to policy statement. Policy guidelines and literature review updated.
02/01/2025	Coding update
09/01/2025	Annual review. No change to policy statement. Literature review updated
04/01/2026	Coding update
09/01/2026	Annual review. No change to policy statement. Literature review updated. Policy title changed from Transurethral Water Vapor Thermal Therapy and Transurethral Water Jet Ablation (Aquablation) for Benign Prostatic Hypertrophy to current one.

Feedback

Blue Shield of California is interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration. Our medical policies are available to view or download at www.blueshieldca.com/provider.

For medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as member health services contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member health services contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT	
BEFORE Red font: Verbiage removed	AFTER Blue font: Verbiage Changes/Additions
Transurethral Water Vapor Thermal Therapy and Transurethral Water Jet Ablation (Aquablation) for Benign Prostatic Hypertrophy 2.01.49 **Policy Statement:** I. Transurethral water vapor thermal therapy is considered **investigational** as a treatment of benign prostatic hyperplasia. II. Transurethral waterjet ablation (aquablation) is considered **investigational** as a treatment of benign prostatic hyperplasia.	**Transurethral Water Vapor Thermal Therapy and Transurethral Water Jet Ablation (Aquablation) for Benign Prostatic Hyperplasia 2.01.49** **Policy Statement:** I. Transurethral water vapor thermal therapy is considered **investigational** as a treatment of benign prostatic hyperplasia. II. Transurethral waterjet ablation (aquablation) is considered **investigational** as a treatment of benign prostatic hyperplasia.