Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 5/1/25**
(See policy history boxes for previous effective dates)

Title: Aquablation (Transurethral Waterjet Ablation) of the Prostate

Description/Background

Benign prostatic hyperplasia (BPH) is a condition that occurs in men when the prostate gland becomes enlarged due to noncancerous proliferation of smooth muscle and epithelial cells of the prostate. As the prostate enlarges, it presses against the urethra, causing lower urinary tract symptoms (LUTS) such as urinary frequency, urinary urgency, trouble starting a urine stream, a weak or an interrupted urine stream, dribbling at the end of urination, nocturia, urinary retention, urinary incontinence, and pain during urination or after ejaculation.

The medical therapeutic options for BPH have evolved significantly over the last 3 decades, and include drugs in two major classifications, alpha-antagonists, and 5-alpha-reductase inhibitors, used alone or in combination therapy. Hormonal drugs have also been used.

If medical therapy fails, or the man wishes to terminate medical therapy, surgical intervention may be considered. The indications to proceed with a surgical intervention for BPH include acute urinary retention, failed voiding trials, and frequent urinary tract infections which may progress to renal insufficiency secondary to obstruction in severe cases.

There are a number of surgical interventions for BPH, including, but not limited to:

- Transurethral resection of the prostate (TURP), which has long been accepted as the criterion standard for relieving bladder outlet obstruction secondary to BPH
- Transurethral incision of the prostate (TUIP)
- Transurethral microwave thermotherapy (TUMT)
- Transurethral needle ablation (TUNA).
- Laser prostatectomy
- Laser-based procedures including contact laser ablation of the prostate (CLAP), holmium laser procedures of the prostate (HoLAP, HoLEP, HoLRP), photoselective laser vaporization of the prostate (PVP), transurethral ultrasound-guided laser induced prostatectomy (TULIP),

and visually-guided laser ablation of the prostate (VLAP, also called non-contact laser ablation of the prostate)

A new minimally invasive surgical technique has been developed which uses a high-velocity, image-guided saline stream to ablate prostatic tissue. According to Procept BioRobotics, the AquaBeam® system is a minimally invasive medical device that allows removal of prostate tissue without leaving a zone of thermal damage on the treated tissue. The AquaBeam® platform technology utilizes a waterjet for automated tissue resection as well as for optical energy delivery for cauterization in the treatment of BPH. No heat sources are used for cutting.

The AquaBeam® system consists of three components: a single-use probe, a robotic hand piece, and a console. The procedure is carried out under transrectal ultrasound imaging. The probe is attached to the hand piece and inserted in the urethra; cystoscopic visualization is available continuously during the procedure. After mapping the desired tissue to be ablated, high-velocity sterile saline is delivered to the prostate tissue via the AquaBeam® probe, which also provides a channel for aspiration of ablated tissue during the procedure.

Regulatory Status

The AquaBeam® system received U.S. Food and Drug Administration (FDA) de novo clearance on April 17, 2017. The AquaBeam® system's intended use is for the resection and removal of prostate tissue in males with lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia.

Medical Policy Statement

Aquablation (transurethral waterjet ablation) of the prostate is considered established as an alternative to open prostatectomy or transurethral resection of the prostate for the treatment of benign prostatic hyperplasia.

Inclusionary and Exclusionary Guidelines

Inclusions:

Aquablation (transurethral waterjet ablation) for the treatment of urinary outlet obstruction due to benign prostatic hyperplasia (BPH) is considered established **ONCE per lifetime** when all of the following criteria are met:

- The individual has prostate volume of 30-150 cc by transrectal ultrasound (TRUS) and persistent moderate to severe symptoms despite maximal medical management including **ALL** of the following attributed to BPH:
    - The individual has an International Prostate Symptom Score (IPSS) of equal to or greater than 12.
    - The individual has a peak urine flow rate (Qmax) less than or equal to 15mL/sec on a voided volume that is greater than 125 cc.
    - The individual has had a failure, contraindication or intolerance to at least three months of conventional medical therapy for LUTS/BPH (e.g., alpha blocker, PDE5 Inhibitor, finasteride/dutasteride).

Exclusions:

- The individual has none of the following:
  - Severe obesity (BMI ≥ 42kg/m2)
  - Known or suspected prostate cancer or a prostate specific antigen (PSA) >10 ng/mL unless there has been a negative prostate biopsy within the last 6 months
  - Bladder cancer, neurogenic bladder, bladder calculus, or clinically significant bladder diverticulum
  - Damaged external urinary sphincter
  - Treatment for chronic prostatitis
  - Diagnosis of urethral stricture, meatal stenosis, or bladder neck contracture
  - Active urinary tract or systemic infection
  - Known allergy to device materials
  - Inability to safely stop anticoagulants or antiplatelet agents preoperatively

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CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

0421T C2596

Other codes (investigational, not medically necessary, etc.):

N/A

Rationale

Aquablation for treatment of BPH has been assessed in a Randomized Controlled Trial (RCT), known as WATER (Waterjet Ablation Therapy for Endoscopic Resection of Prostate Tissue).[1] WATER was a noninferiority trial comparing aquablation with TURP in 181 participants at 17 sites in 4 countries (Table 1). Participants were men ages 45 to 80 years with moderate-to-severe LUTS, defined as an IPSS score greater than or equal to 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 end point 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,[1] 12-month results in Gilling et al (2019),[2] 3-year results in Gilling et al (2020)[3], and 5 year results in Gilling et al (2022).[9] Additionally, a synthesis of the trial results up to 12 months was reported in a Cochrane systematic review conducted by Hwang et al(2019).[4]

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 15.1points 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 1. Summary of Key Randomized Controlled Trial Characteristics

Trial	Countries	Sites	Dates	Participants	Interventions

					Active	*Comparator*
WATER [1, 2] NCT02505919	US, UK, Australia, New Zealand	17	October 2015-December 2016	Men age 45-80 years with a prostate size between 30-80mL, moderate-to severe LUTS (IPSS 10 to ≥ 12), and (Qmax) < 15 mL/s.	Aquablation n=65	TURP n=116

IPSS: International Prostate Symptom Score: RCT: randomized controlled trial; 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 2. The reviewers assessed the certainty of the evidence for each outcome using the GRADE approach.[4] 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. They 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 2. WATER Trial Results at 12 months (Adapted from Hwang et al [2019][4,])

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 confidence interval 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: confidence interval crosses assumed threshold of minimal clinically important difference, high risk of performance and attrition bias)

Source: adapted from Hwang et al (2019)4,

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 years (Table 3).[3, 9] 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 any time point. Efficacy was maintained through 5 years as well, but safety results were not reported beyond 3 years.

Table 3. WATER Trial Results at 3 Years 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 Adverse Events Subjects (%)
WATER[3] NCT02505919							
3 year results							
Aquablation	14.4 (6.8)	64%	78%	3.2 (1.8)	11.6	5/116 (4.3%)	0-3 months: 7 (6.0%) 3 months - 1 year: 5 (4.3%) 1-2 years: 8 (6.9%) 2-3 years: 4 (3.4%)
TURP	13.9 (8.6)	61%	82%	3.2 (1.7)	8.2	1/65 (1.5%)	0-3 months:4 (6.2%) 3 months - 1 year: 5 (7.7%) 1-2 years: 2 (3.1%) 2-3 years: 1 (1.5%)
Difference	0.6 (-3.3 to 2.2)	3%	4%	0	3.3 (-0.5-7.1)	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; 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.

In 2017 Gilling et al reported on a prospective, single arm, multicenter trial at a total of 3 centers in Australia and New Zealand with 1-year followup.[5] Participants were men 50 to 80 years old with moderate to severe lower urinary tract symptoms as determined by urodynamics. All patients underwent aquablation under image guidance. Primary end points included procedural and perioperative safety. The main clinical end point was the change from baseline in I-PSS (International Prostate Symptom Score). Other secondary end points included uroflow measures, prostate volume on transrectal ultrasound and detrusor pressure. Detrusor pressure at maximum flow was only measured at 6 months. Twenty-one men underwent aquablation at a mean age of 69.7 years (range 62 to 78). Prostate volume was 57.2 ml (range 30 to 102). Procedural duration averaged 38 minutes with a mean aquablation treatment time of 5 minutes. All but 1 subject were catheterized for 1 day only and 19 of 21 were discharged home the day after the procedure. Detrusor pressure at maximum flow decreased from 65 cm H_2O at baseline to 39 cm H_2O at 6 months ($p < 0.0027$). Prostate volume decreased from 57 ml at baseline to 35 ml ($p < 0.0001$). Mean I-PSS score improved from 23.0 at baseline to 6.8 at 12 months ($p < 0.0001$) and maximum urinary flow increased from 8.7 to 18.3 ml per second ($p < 0.0001$). There were no important perioperative adverse events. No urinary incontinence developed and sexual function was preserved postoperatively. The authors concluded that this phase II study provided early evidence to support the safety and effectiveness of aquablation for symptomatic benign prostatic hyperplasia.

In 2015, Gilling et al had reported on a first-in-man safety and feasibility trial that evaluated AquaBeam® for the targeted removal of prostatic tissue in 15 men with moderate to severe LUTS due to BPH who had not responded adequately to standard medical therapy.[6] This prospective, single-arm, single-center trial enrolled men aged 59 to 86 years (mean age, 73 years) with a mean prostate size of 54 ml (range, 27 to 85 ml). All AquaBeam® procedures were carried out under general anesthesia. Two different versions of the system were used. The second system, which was used in the last eight patients, differed from the original version in that the ultrasound images were integrated into the console screen, an integrated aspiration pump was added, and the laser for cautery was eliminated. The laser cautery function used in early cases was abandoned, as it was found to be ineffective.

The primary study outcome was safety, as measured by the incidence of 30-day adverse events. Secondary endpoints included catheterization time, International Prostate Symptom Score (IPSS), International Index of Erectile Function (IIEF), and Incontinence Severity Index (ISI) scores. Urodynamic parameters, including peak flow rate (Qmax) and post void residual volume (PVR), were also measured, in addition to changes in prostatic volume as determined by transrectal ultrasound at 6 months. Procedural success was 100%; no procedure- or device-related adverse events were reported. There were no reports of a serious 30-day adverse event. Catheters were removed within 24 hours of the procedure in all but one patient. The mean procedure time was 48 minutes, with a mean aquablation treatment time of 8 minutes. Five patients required recatheterization within 30 days of discharge for urinary retention; all five were subsequently able to void. Three patients experienced dysuria that resolved spontaneously, and three experienced hematuria not requiring intervention. At 1 month, there were statistically significant improvements in IPSS (P=0.0016), Qmax (P=0.0268), and PVR (P=0.0216). Fourteen patients were available for follow-up at 6 months; there were further improvements in IPSS (P<0.0001), Qmax (P=0.0005), and PVR (P=0.0134) at 6 months. The authors concluded that these preliminary results from this initial study demonstrated aquablation of the prostate is technically feasible with a safety profile comparable to other BPH technologies. The combination of surgical mapping by the operating surgeon and the high-velocity saline has the potential to provide a promising technique for delivering a conformal, quantifiable, and standardized heat-free ablation of the prostate. Advantages of this technique include reduction in resection time compared to other endoscopic modalities as well as the potential to preserve sexual function.

Suarez-Ibarrola et al (2019) summarized the contemporary literature on aquablation and evaluating its safety and efficacy for the treatment of symptomatic benign prostatic enlargement (BPE).[7] Sixteen studies, including 446 patients treated with aquablation eligible for data extraction and analysis. A RCT comparing aquablation to transurethral resection of the prostate (TURP) with 6-month, 1-year, and 2-year outcomes, three single-center and single-arm studies, three multicenter and single-arm studies, and five subgroup analyses. Aquablation improved International Prostate Symptom Score (IPSS), IPSS-quality of life (IPSS-QoL), maximum urinary flow rate (Q) and post void residual (PVR) from baseline to last follow-up in all prospective studies. At 2-year follow-up, aquablation showed non-inferior symptom relief compared to TURP, with a lower risk of anejaculation favoring aquablation and no significant differences regarding Clavien-Dindo events. Although a significant hemoglobin drop was reported in all aquablation single-arm studies and when compared to TURP, it did not translate into increased transfusion rates. This study provides some support of the safety of aquablation assessed by procedure-related adverse events.
Nguyen et al (2020) compared the outcomes of aquablation in 30-80 ml prostates with those in 80-150 ml prostates.[8] Waterjet Ablation Therapy for Endoscopic Resection of prostate tissue

(WATER [W-I]; NCT02505919) is a prospective, double-blind, multicentre, international clinical trial comparing Aquablation and transurethral resection of the prostate (TURP) for the treatment of LUTS/BPH in prostates between 30 and 80 mL. WATER II (WII; NCT03123250) is a prospective, multicentre, single-arm international clinical trial of Aquablation in prostates between 80 and 150 mL. We compare baseline parameters and 12-month outcomes in 116 W-I and 101 W-II study patients. Students' t-test or Wilcoxon tests were used for continuous variables and Fisher's test for binary variables. The mean (SD) operative time was 33 (17) and 37 (13) min in W-I and W-II, respectively. Actual treatment time was 4 and 8 min in W-I and W-II, respectively. The mean change in the International Prostate Symptom Score was substantial averaging (at 12 months) 15.1 in W-I and 17.1 in W-II (P = 0.605). By 3 months, Clavien-Dindo grade ≥II events occurred in 19.8% of W-I patients and 34.7% of W-II patients (P = 0.468). The authors concluded that aquablation clinically normalizes outcomes between patients with 30-80 mL prostates and patients with 80-150 mL prostates treated for LUTS/BPH, with an expected increase in the risk of complications in larger prostates.

The OPEN WATER study is a multi-center, prospective, all-comers study of Aquablation therapy in a real-world setting enrolling 178 patients in five community-based sites.[10] This study evaluated Aquablation with prostates ranging in size from 20 to 150 mL with patients ranging in age from 39 to 88 years.

In a retrospective analysis, Kasraeian et al (2020) characterized procedure variables and outcome data from men undergoing the Aquablation Therapy of the prostate procedure for lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH).[11] These researchers examined the safety and efficacy of robotically guided waterjet-based prostate resection in the 1st study of all-comers in a single-center, commercial setting in the United States. A total of 55 men ages ranging from 50 to 84 years underwent the Aquablation of the prostate between July 2018 and December 2019. Mean prostate volume (PV) was 100 cc, and 85 % had a prominent, obstructing middle lobe. Operative time averaged 59 mins, and the mean hemoglobin (Hb) drop was 1 g/dL. A substantial improvement of 80 % (17 points) was observed in BPH symptoms scores. By uroflowmetry, Qmax improved by 182 % (14 ml/sec). Men with PV of greater than 100 cc had similar hospital length of stay (LOS), BPH symptom reduction, and Qmax improvement compared to those with volume of less than 100 cc. The authors concluded that in the setting of a community private urology practice, Aquablation Therapy was safe and effective for the treatment of men with BPH regardless of prostate shape or prostate size.

The OPEN WATER and Kasraeian studies included 13 patients (8 and 5 patients, respectively) with ages greater than 80 at the time of the procedures. Three-month follow up on 12 of the 13 patients demonstrated a 14-point decline in the International Prostate Symptom Score (IPSS), which is consistent with the overall findings across all ages in both the OPEN WATER and Kasraeian studies (as well as consistent with the findings in the WATER and WATER II studies). In addition, the maximum urinary flow rate (Qmax) more than doubled in the patients over 80 where 12-month follow up data are available.

SUMMARY OF EVIDENCE

For individuals with benign hyperplasia of the prostate who receive aquablation of prostate tissue, the evidence includes one first-in-man safety and feasibility trial and one prospective,

single-arm, multicenter trial, and one noninferiority RCT of aquablation compared to TURP in 187 patients with a 5 years of follow-up. The main clinical end point was the change from baseline in I-PSS (International Prostate Symptom Score). Other secondary end points included uroflow measures, prostate volume on transrectal ultrasound and detrusor pressure. The outcomes of interest in the RCT study 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 endpoint was the development of Clavien-Dindo persistent grade 1, or 2 or higher operative complications at 3 months. At 6 months, mean I-PSS 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). Gilling et al (2020) and Gilling et al (2022) reported trial results at 3 years and 5 years, and observed 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 any time point. Efficacy was maintained through 5 years as well, but safety results were not reported beyond 3 years.[3,9] The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

PRACTICE GUIDELINES AND POSITION STATEMENTS

American Urological Association (AUA)

In 2023, the American Urological Association published guidelines on the surgical evaluation and treatment of lower urinary tract symptoms (LUTS) attributed to benign prostatic hyperplasia (BPH) and included the following recommendations[12]

- 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)

National Institute for Health and Care Excellence

In 2020, the NICE issued the following guidance on Rezum for treatment of LUTS secondary to BPH:[13]

"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 cm3 and 80 cm3)."

In 2023, NICE updated guidance on transurethral water jet ablation for LUTS caused by BPH. 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)." [14]

A Medtech innovation briefing was released by NICE in January 2023 but guidance specific to aquablation is awaiting development.[15]

Government Regulations

National:

No National Coverage Decision on this procedure.

Local:

LCD L35490, Category III Codes, effective on or after 11/17/2024.

This LCD provides group 1, group 2 and group 3 codes that are determined by WPS GHA to be reasonable and medically necessary, the code 0421T is not listed in any of these groups. The code 0421T is listed under Local Coverage Article: Billing and Coding: Transurethral Waterjet Ablation of the Prostate (A58209) Original effective date: 12/27/2020, Revision date: 10/27/22.

Wisconsin Physicians Insurance Service Corporation (WPS)
Local Coverage Determination (LCD): L38682 Transurethral Waterjet Ablation of the Prostate
Original effective date: 12/27/2020, Revision Effective Date: 09/26/24

Covered Indications
Treatment for LUTS/BPH will be considered reasonable and necessary **ONCE per lifetime** in patients with:

1. **All** of the following indications:
    a. Prostate volume of 30-150 cc transrectal ultrasound (TRUS)[4,5],
    b. Persistent moderate to severe symptoms despite maximal medical management including **ALL** of the following:
        i. International Prostate Symptom Score (IPSS) ≥12[4]
        ii. Maximum urinary flow rate (Qmax) of ≤15 mL/s[4] (voided volume greater than 125 cc)
        iii. Failure, contraindication or intolerance to at least three months of conventional medical therapy for LUTS/BPH (e.g., alpha blocker, PDE5 Inhibitor, finasteride/dutasteride)
2. Only treatment using an FDA approved/cleared device will be considered reasonable and necessary.

Limitations
Transurethral waterjet ablation of the prostate is not considered reasonable and necessary for patients with the following:

1. Body mass index ≥ 42kg/m2[6]
2. Known or suspected prostate cancer (based on NCCN Prostate Cancer Early Detection guidelines[7]) or a prostate specific antigen (PSA) >10 ng/mL, unless the patient has had a negative prostate biopsy within the last 6 months.
3. Bladder cancer, neurogenic bladder, bladder calculus or clinically significant bladder diverticulum[6]
4. Active urinary tract or systemic infection[6]
5. Treatment for chronic prostatitis[6]
6. Diagnosis of urethral stricture, meatal stenosis, or bladder neck contracture[6]
7. Damaged external urinary sphincter[6]
8. Known allergy to device materials[8]
9. Inability to safely stop anticoagulants or antiplatelet agents preoperatively.[8]

Wisconsin Physicians Insurance Service Corporation (WPS)
Local Coverage Article:
Billing and Coding: Transurethral Waterjet Ablation of the Prostate (A58209)
Original effective date: 12/27/2020, Revision date: 10/27/22

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)
C2596	Probe, image-guided robotic, waterjet ablation

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

Prostatic Urethral Lift Procedure for the Treatment of BPH

References

1. Gilling P, Barber N, Bidair M, et al. WATER: A Double-Blind, Randomized, Controlled Trial of Aquablation (R) vs Transurethral Resection of the Prostate in Benign Prostatic Hyperplasia. J Urol. May 2018; 199(5): 1252-1261. PMID 29360529

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11. Kasraeian A, Alcantara M, Alcantara KM, Altamirando JA, Kasraeian A. Aquablation for BPH. Can J Urol. 2020 Oct;27(5):10378-10381.
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13. National Institute for Health and Care Excellence (2020). Rezum for treating lower urinary tract symptoms secondary to benign prostatic hyperplasia. https://www.nice.org.uk/guidance/mtg49/chapter/1-Recommendations.
14. National Institute for Health and Care Excellence (2023). Transurethral water jet ablation for lower urinary tract symptoms caused by benign prostatic hyperplasia. [IPG770]. https://www.nice.org.uk/guidance/ipg770.
15. National Institute for Health and Care Excellence (NICE). Aquablation robotic therapy for lower urinary tract symptoms caused by benign prostatic hyperplasia. January 1, 2023. https://www.nice.org.uk/advice/mib315/chapter/Clinical-and-technical-evidence.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through January 2, 2025, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
9/1/16	6/21/16	6/21/16	Joint policy established
9/1/17	6/20/17	6/20/17	Routine maintenance. No change in policy status.
9/1/18	6/19/18	6/19/18	Routine policy maintenance. No change in policy status.
9/1/19	6/18/19		Routine policy maintenance. No change in policy status.
9/1/20	6/16/20		Updated rationale section, added reference # 5 and 6. Added code C2596. No change in policy status.
9/1/21	6/15/21		Routine policy maintenance. No change in policy status.
3/1/22	TABLED		10/29/21 Updated Regulatory section and the final signature page - The AquaBeam® system received U.S. Food and Drug Administration (FDA) de novo clearance on April 17, 2017. The AquaBeam® system's intended use is for the resection and removal of prostate tissue in males suffering from lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia. Updated policy reflecting BCBSA's update from July 2021 - New indication and investigational policy statement added for aquablation to Blue Cross Blue Shield Association Medical Policy Reference Manual. Policy #2.01.49 - Transurethral Water Vapor Thermal Therapy. Policy title changed to reflect new indication- Transurethral Water Vapor Thermal Therapy and Transurethral Water Jet Ablation(Aquablation) for Benign Prostatic Hypertrophy.
5/1/23	3/29/23		Policy status of Aquablation changed from E/I to EST. This would be a divergent from BCBSA. Literature supports coverage of aquablation.

			Many payors have moved to covering Aquablation. Vendor review: NA Post-JUMP •Following Medicare guidelines - added Once per lifetime under the Inclusionary and Exclusionary Guidelines to the below. Aquablation (transurethral waterjet ablation) for the treatment of urinary outlet obstruction due to benign prostatic hyperplasia (BPH) is considered established **ONCE per lifetime** when all of the following criteria are met: (ky) 6/20/23: Corrected BCN Benefit page. changed "noncovered" to "covered; criteria apply"
5/1/24	2/20/24		Routine maintenance Based on the OPEN WATER and Kasraeian studies and Wisconsin Physicians Insurance Service Corporation (WPS) Local Coverage Determination (LCD): L38682 Transurethral Waterjet Ablation of the Prostate Original – under the JUMP policy Inclusions - the requirement of age ≤80 was removed. Vendor: N/A (ky)
5/1/25	2/18/25		Routine Maintenance Vendor: N/A (ky)

Next Review Date: 1st Qtr. 2026

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: AQUABLATION (TRANSURETHRAL WATERJET ABLATION) OF THE PROSTATE

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered; criteria apply.
BCNA (Medicare Advantage)	See government section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

N/A