VHA Office of Integrated Veteran Care
Clinical Determination and Indication
Transurethral Waterjet Ablation for
Benign Prostatic Hyperplasia

CDI Number: 00009

Original Effective Date: June 1, 2024

Last Review Date: June 1, 2024

I. Disclaimer

This document is currently in draft and is intended to be used as a reference for non-VA providers and not intended to replace clinical judgment when determining care pathways. These guidelines do not guarantee benefits or constitute medical advice.

II. Clinical Determinations and Indications

This document provides information only on Transurethral Waterjet Ablation for benign prostatic hyperplasia (BPH). Please refer to the American Urology Association's BPH guidelines for a comprehensive guide to managing BPH.

a. Indications for Transurethral Waterjet Ablation

Transurethral waterjet ablation, (also known as aquablation) is indicated for the treatment of BPH. It will be considered **medically necessary** when performed **ONCE** in Veterans that meet **ALL** the following criteria:

- Prostate volume of 50-200 cc by diagnostic imaging
- Persistent moderate to severe symptoms despite maximal medical management including **ALL** the following:
  - International Prostate Symptom Score (IPSS) ≥12 AND
  - Maximum urinary flow rate (Qmax) of ≤15 mL/s (voided volume greater than 125 cc) AND
  - Failure, contraindication, intolerance, or patient refusal to at least three months of conventional medical therapy for Lower Urinary Tract Symptoms (LUTS) with BPH (e.g., alpha-blocker, PDE5 Inhibitor, finasteride/dutasteride)
- Must use an FDA-approved device to perform the procedure

Note: Patient receiving transurethral waterjet ablation must be able to tolerate general anesthesia.

- Spinal anesthesia may be considered in special circumstances; however general anesthesia is the preference for this procedure

b. Limitations/Exclusions

For all the conditions/indications not listed in section II.a. of this document, transurethral waterjet ablation is considered **not medically necessary** due to insufficient evidence of efficacy and safety.

Conditions for which transurethral waterjet ablation is **not medically necessary** include, but are not limited to, the following:

- Chronic prostatitis
- Prostate cancer
- BPH with the presence of a large middle lobe
- Neurogenic bladder

c. Description of Treatment

The AQUABEAM System is an image-guided prostate tissue removal system that uses a high-velocity water jet to ablate a predetermined volume of prostatic tissue.

Aquablation using the AQUABEAM system (PROCEPT BioRobotics) combines the precision of autonomous robotic execution to deliver a high-velocity waterjet via a cystoscopic handpiece with accurate anatomical prostatic mapping using real-time transrectal ultrasound imaging.

The initial part of the surgery involves careful treatment planning tailored to the prostatic anatomy with the preservation of important nearby landmarks, followed by a targeted high-velocity waterjet stream delivered to ablate the obstructing prostatic tissue without use of any heat.

Pre-treatment, transrectal ultrasound (TRUS) maps out the specific region of the prostate to be resected while limiting resection in key anatomical areas such as the bladder neck, ejaculatory ducts, and external urinary sphincter. The resection is then executed automatically via a robotic arm. Multidimensional imaging to map and create the exact treatment plan occurs during the procedure. The whole procedure takes less than an hour.

Following the ablation and removal of the handpiece, a cystoscopic bladder washout and establishment of hemostasis is performed. Patients may go home with a urinary catheter.

The most common side effects of the procedure are mild and transient and may include mild pain or difficulty when urinating, discomfort in the pelvis, blood in the urine, inability to empty the bladder or a frequent and/or urgent need to urinate, and bladder or urinary tract infection. Other risks include ejaculatory dysfunction and a low risk of injury to the urethra or rectum where the devices gain access to the body for treatment.

III. Background and Supporting Information

The following information is for reference purposes only in accordance with the medical benefits package outlined in 38 C.F.R. § 17.38 (b). Each subsection supports VA's determinations for medical necessity and alignment with generally accepted standards of medical practice.

a. Background of Benign Prostatic Hyperplasia

Benign prostatic hyperplasia (BPH) is a histological diagnosis characterized by an increased number of epithelial and stromal cells in the prostate. It is common in individuals with prostates over the age of 40, and the incidence increases with age. In the United States, 8 million individuals with prostates over the age of 50 years suffer from BPH. In many cases BPH is asymptomatic, however, symptoms may occur with prostate enlargement and compression of the urethra leading to bothersome lower urinary tract symptoms (LUTS), including voiding symptoms such as hesitancy, weak stream, straining, prolonged voiding, and storage symptoms (frequency, urgency, and nocturia).

LUTS can be subdivided into symptoms of urinary storage (e.g., urgency, frequency, and nocturia), urinary voiding (e.g., straining to void, urinary intermittency, dysuria, and hesitancy), and post-voiding symptoms (e.g., sensation of incomplete bladder emptying and post-void urinary dribbling). LUTS/BPH can have a significant impact on the quality of life and can cause serious complications such as infections, bleeding, calculus formation, urinary retention and decline of renal function when untreated.

First line treatment generally consists of treatment with medications such as alpha blockers, PDE5 Inhibitors, or finasteride/dutasteride. If treatment with medications is not successful, surgical options may be considered. Transurethral resection of the prostate (TURP) and open simple prostatectomy (OSP) are the standard surgical treatments for LUTS/BPH and are highly effective and provide improved outcomes in urinary functions. However, neither TURP nor OSP are without considerable perioperative complication and morbidity.

Recently, new techniques have emerged as alternatives for the resection of the prostate to manage LUTS in individuals with BPH. One such surgery is transurethral waterjet ablation; a water-based surgical therapy that combines image guidance and robotics to remove prostatic tissue. The system works by pumping high pressure saline (500 to 8000 pounds per square [PSI]) through a probe nozzle to cut and dissect tissue at predetermined system parameters.

Recent trials have shown that Transurethral Waterjet Ablation is safe and effective in the treatment of symptomatic BPH while maintaining sexual preservation.

b. Research, Clinical Trials, and Evidence Summaries

The American Urological Association's guidelines on the Management of BPH/LUTS (2021) are based on the best available evidence of literature and scientific data that identify characteristics and components of quality of care. It provides a useful reference on the effective evidence-based surgical management of male lower urinary tract symptoms secondary to benign prostatic hyperplasia (LUTS/BPH).

The American Urological Association includes robotic waterjet treatment (RWT) in its surgical practice guidelines as a treatment option for patients with LUTS/BPH provided prostate volume 30-80cc. (Conditional Recommendation; Evidence Level: Grade C).

- Conditional Recommendations are non-directive statements used when the evidence indicates that there is no apparent net benefit or harm or when the balance between benefits and risks/burdens is unclear
- Evidence Level: Grade C means that the balance between Benefits & Risks/Burdens is unclear. Alternative strategies may be equally reasonable. Better evidence is likely to change confidence

According to the American Urological Association, the technique is not in the MIST (Minimally Invasive Surgical Technique) category as patients must undergo general anesthesia.

Studies and recommendations demonstrate the safety and effectiveness of aquablation as an option for individuals aged equal to or less than 80, with moderate to severe LUTS due to BPH as indicated by International Prostate Symptom Score (IPSS) equal to or greater than 12 and a 30-80 cc prostate. In addition, the ability to preserve sexual function is a major consideration for this treatment.

Nguyen et. al (2019) compared the outcomes of aquablation in 30-80mL prostates from the WATER I clinical trial with the outcomes in 80-150mL prostates from the WATER II clinical trial to determine if the effectiveness of aquablation is independent of prostate size. The team found that the effectiveness of aquablation is independent of prostate size and is a safe and effective treatment option in small-to-moderate sized (30–80 mL) and large-to-very-large (80–150 mL) prostates.

Initial clinical experience reported in 2016, the WATER (Waterjet Ablation Therapy for Endoscopic Resection) of prostate tissue trial, a PHASE III multicenter international, double-blind, randomized, non-inferiority study (cohort consisted of individuals aged 45–80 year with a prostate of 30–80 cm) with 181 subjects comparing aquablation (116/181) to TURP (65/181) showed a change in the IPSS at six months; scores decreased by 16.9 points and

points for aquablation and 16.1 for TURP, respectively. At two years, IPSS score improvement was sustained (14.7 in aquablation and 14.9 in TURP).

A 2019 Cochrane Review based on 1-year aquablation trial results, found evidence of similar results with TURP to be of moderate certainty related to the urologic symptom score (IPSS) primary outcome measure.

In a study by Nguyen DD, Barber N, Bidair M et al, the authors conclude outcomes and effectiveness of aquablation are comparable and are independent of prostate size with the expectation that with larger prostates a higher risk of complication is possible.

Canadian Urological Association (CUA) 2018 guidelines give a “conditional recommendation based on moderate-quality evidence” that aquablation may be offered to individuals “interested in preserving ejaculatory function, with prostates <80 cc, with or without a middle lobe”.

A 2018 National Institute for Health and Care Excellence (NICE) systematic review based on 6-month WATER results concluded the procedure should only be used with “special arrangements,” a defined designation meaning there are uncertainties about safety and effectiveness.

In an April 2020 study by Desai et. al. provides strong evidence that aquablation provides excellent mid-term (2 year) long-term relief of LUTS related to BPH.

Five-year outcomes from WATER (NCT02505919) demonstrate BPH symptom reduction and urinary flow rate improvement similar to TURP in participants with prostate sizes between 30 and 80 cc.

A study of Robotic Water Jet Ablation vs TURP functional outcomes from two FDA clinical trials conducted in 2022 by The Weill Medical College of Cornell University/ New York Presbyterian and Icahn School of Medicine at Mount Sinai concluded that Robotic Waterjet Treatment (RWT) and TURP are effective BPH therapy in patients who truly failed medical therapy, and RWT demonstrated this in a much broader prostate size range. Functional outcomes did not statistically differ between RWT and TURP at baseline and at 36 months. TURP has classically been that option and in the WATER studies, RWT has demonstrated non-inferiority. In a pre-specified analysis, RWT showed superior results in symptom reduction compared to TURP in prostate sizes 50-80cc. This sub-analysis of the medical therapy failure cohort further reinforces the role of these therapies as the treatment of choice for medical therapy failures including those who desire to limit their sexual adverse events from surgical therapies.

c. U.S. Food & Drug Administration (FDA) Information

VA generally only approves use of medical devices that have received at least FDA clearance for 510(k) Premarket Notification. The FDA has determined these Class II devices are substantially equivalent (SE) to legally marketed predicate devices and may be marketed in the U.S.

To search for devices that have received FDA 510(k) clearance or Premarket Approval (PMA), please visit the FDA Devices database.

Information	Description
Product Name	AQUABEAM Robotic System
PMN Applicant	PROCEPT BioRobotics Corporation
Address	900 Island Drive Suite 101 Redwood Shores, CA 94065
Approval Date	October 6, 2021
Approval Letter	K212835.pdf (fda.gov)

d. Medicare Coverage Determinations

Available Medicare coverage determinations are listed below as a resource. VA and Medicare are governed by separate laws and regulations; thus, VA coverage determinations may be different.

NCD Number	Name	Effective Date
None	N/A	N/A

LCD Number	Contractor	Revision Effective Date
L38726	First Coast Service Options	12/27/2020
L38705	Noridian Healthcare Solutions	12/27/2020
L38707	Noridian Healthcare Solutions	12/27/2020
L38712	Novitas Solutions	12/27/2020
L38549	Palmetto GBA	01/29/2023
L38682	WPS Insurance Corporation	10/27/2022

- NCD: National Coverage Determination
- LCD: Local Coverage Determination

IV. Definitions

Term	Definition
Ablation	The removal or destruction of a body part or tissue or its function
Benign	Non-cancerous; not harmful in effect
Bladder Calculus	Bladder Calculi or stones are hardened clumps of minerals that form in the bladder. Urinary stasis, such as with BPH, radiation therapy, schistosomiasis, bladder augmentation surgery, urethral strictures, and the presence of bladder diverticula are predisposing factors to bladder stone formation. Stones can also form in healthy individuals without anatomic defects, foreign bodies, strictures, or infections
Bladder Diverticulum	A bladder diverticulum is an out-pouching of the bladder that occurs when a part of the bladder lining protrudes through a weakness in the bladder wall. These occur either congenitally or as an acquired condition from bladder outlet obstruction, neurogenic bladder conditions, or from prior bladder surgery
Bladder Neck Contracture	Scar tissue in the bladder neck can make the bladder neck narrow, and that makes it more difficult for urine to flow through it. This is known as bladder neck contracture
Hyperplasia	The enlargement of an organ or tissue caused by an increase in the reproduction rate of its cells
Histology	The study of the microscopic structure of tissues
IPSS	International Prostate Symptom Score is an eight-question written screening tool used to screen for, rapidly diagnose, track the symptoms of, and suggest management of the symptoms of BPH
Meatal Stenosis	Narrowing of the opening of the urethra, the tube through which urine leaves the body
Minimally Invasive Surgical Technique (MIST)	These are generally low risk procedures that can be performed in an outpatient setting (e.g., in an office or ambulatory care setting). Typically, in this technique, the surgeon does not remove tissue but rather alter the anatomy to some degree. Procedures that are considered MIST have a low risk for adverse events. Long term durability is often less than resection/tissue removal procedures
Morbidity	Refers to having a disease or a symptom of disease, or to the amount of disease within a population. Morbidity also refers to medical problems caused by a treatment

Term	Definition
Neurogenic Bladder	Neurogenic bladder is the name given to a number of urinary conditions in people who lack bladder control due to a brain, spinal cord or nerve problem. This nerve damage can be the result of diseases such as multiple sclerosis, Parkinson's disease or diabetes. It can also be caused by infection of the brain or spinal cord, heavy metal poisoning, stroke, spinal cord injury, or major pelvic surgery. People who are born with problems of the spinal cord, such as spina bifida, may also have this type of bladder problem
Nocturia	The need to get up at night on a regular basis to urinate
Prostatectomy	A surgical procedure for the partial or complete removal of the prostate
Transurethral	Passing through or performed by way of the urethra
Transrectal	Passing through or performed by way of the rectum
Urethral Stricture	A urethral stricture is a narrowing of the urethra, usually caused by scar tissue, causing obstructive symptoms
Uroflowmetry	A test that measures the volume of urine released from the body, the speed with which it is released, and how long the release takes

V. References

Aquabeam autonomous surgical robot for prostate resection: Procept. PROCEPT BioRobotics. (2022). Retrieved April 26, 2023, from https://www.procept-biorobotics.com/aquabeam-surgical-robotic-system/

Dec, M., Andruszkiewicz, P. (2016). Anaesthesia for minimally invasive surgery. Wideochirurgia i inne techniki maloinwazyjne = Videosurgery and other miniinvasive techniques. Retrieved May 4, 2023, from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4729732/

Gilling P, Anderson P, Tan A. (n.d.). Aquablation of the Prostate for Symptomatic Benign Prostatic Hyperplasia: 1-Year Results. UpToDate. Retrieved April 27, 2023, from https://www.uptodate.com/contents/surgical-treatment-of-benign-prostatic-hyperplasia-bph/abstract/65

Ivanov, A., Antonov, P., Hristova-Atanasova, E., & Uchikov, P. (2023). Changes in Lower Urinary Tract Symptoms in Benign Prostatic Hyperplasia Patients Affected by Covid-19. Urologia internationalis, 1–5. Advance online publication. https://doi.org/10.1159/000528975

Lahham, S., & Gutierrez, S. (2021). Diagnosis of Bladder Diverticula with Point-of-Care Ultrasound. Clinical practice and cases in emergency medicine, 5(4), 466–467. https://doi.org/10.5811/cpcem.2021.7.53199

Landmark Medical Center. (2022). Aquablation. Retrieved May 2, 2023, from https://landmarkmedical.org/our-services/ambulatory-surgery-unit/aquablation/#:~:text=Aquablation%20therapy%20is%20performed%20in,and%20involves%20an%20overnight%20stay

Lerner LB, McVary, KT, Barry MJ et al: Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia: AUA Guideline part I, initial work-up and medical management. J Urol 2021; 206:806,818.

Leslie SW, Sajjad H, Murphy PB. (2023). Bladder Stones. Stat Pearls Publishing. Retrieved April 26, 2023, from: https://www.ncbi.nlm.nih.gov/books/NBK441944/

Lim Ng, K., & Barber, N. (2019). Prostatic hydroablation (Aquablation): A new effective ultrasound guided robotic waterjet ablative surgery for treatment of benign prostatic hyperplasia. 72(8), 786–793.

MacRae, C., Gilling, P. (2016). How I do it: Aquablation of the prostate using the A beam system. Retrieved April 26, 2023, from https://www.canjurol.com/html/free-articles/JUv23_I06_16_FREE_DrGilling.pdf

Medicare Coverage Database (n.d.) Retrieved May 4, 2023, from https://www.cms.gov/medicare-coverage-database/search.aspx

Nguyen, D. D., Barber, N., Bidair, M., Gilling, P., Anderson, P., Zorn, K. C., Badlani, G., Humphreys, M., Kaplan, S., Kaufman, R., So, A., Paterson, R., Goldenberg, L., Elterman, D., Desai, M., Lingeman, J., Roehrborn, C., & Bhojani, N. (2020). Waterjet Ablation Therapy for Endoscopic Resection of prostate tissue trial (WATER) vs WATER II: comparing Aquablation therapy for benign prostatic hyperplasia in 30-80 and 80-150 mL prostates. BJU international, 125(1), 112–122. https://doi.org/10.1111/bju.14917

NCI Dictionary of cancer terms. (n.d.). National Cancer Institute. https://www.cancer.gov/publications/dictionaries/cancer-terms/def/morbidity

PROCEPT BioRobotics Corporation. (2022). Aquablation therapy faqs: Procept. PROCEPT BioRobotics. Retrieved May 2, 2023, from https://www.procept-biorobotics.com/aquablation-therapy/aquablation-faqs/

PROCEPT BioRobotics Corporation. (n.d.). Procept biorobotics. BPH Surgery Reimagined - Aquablation. Retrieved April 27, 2023, from https://www.procept-biorobotics.com/wp-content/uploads/2020/06/ML0149.B-Aquablation-Brochure-English.pdf

Centers for Medicare & Medicaid Services. (n.d.). Response to comments: Transurethral waterjet ablation of the prostate. CMS.gov. Retrieved May 5, 2023, from https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=58539&ver=3

RWJBarnabas Health. (n.d.). Aquablation therapy - Monmouth Medical Center Southern Campus. RWJBarnabas Health. Retrieved April 27, 2023, from https://www.rwjbh.org/monmouth-medical-center-southern-campus/treatment-care/urology/aquablation-therapy/

Soltesz, D. (2019). AUA amends clinical practice guidelines to include Procept Biorobotics' Aquablation therapy as a standard of care option for the treatment of enlarged prostate. BioSpace. Retrieved April 26, 2023, from https://www.biospace.com/article/releases/aua-amends-clinical-practice-guidelines-to-include-procept-biorobotics-aquablation-therapy-as-a-standard-of-care-option-for-the-treatment-of-enlarged-prostate/#:~:text=The%20AQUABEAM%C2%AE%20Robotic%20System,for%20the%20treatment%20of%20BPH

Te, A. E., Sze, C., Kaplan, S. A., & Chughtai, B. (2023). Surgical treatment for BPH refractory to medication: robotic water jet ablation vs. TURP functional outcomes from two FDA clinical trials. The Canadian journal of urology, 30(1), 11408–11413.

Te, A., Sze, C., Kaplan, S., Chughtai, B. (2022). Surgical treatment for BPH refractory to medication: Robotic Water Jet Ablation vs TURP functional outcomes from two FDA clinical trials. Surgical Treatment for BPH Refractory to Medication: Robotic Water Jet Ablation vs TURP functional outcomes from two FDA clinical trials. Retrieved May 2, 2023, from https://www.researchsquare.com/article/rs-1832879/v1

The University of Iowa. (2022). Preparing for bladder neck contracture repair. University of Iowa Hospitals & Clinics. https://uihc.org/educational-resources/preparing-bladder-neck-contracture-repair#:~:text=Scar%20tissue%20in%20the%20bladder,the%20bladder%20and%20the%20kidneys

University of Michigan Health. (n.d.). Neurogenic bladder. Michigan Medicine. https://www.uofmhealth.org/conditions-treatments/adult-urology/neurogenic-bladder#:~:text=Neurogenic%20bladder%20is%20the%20name,)%2C%20Parkinson%27s%20disease%20or%20diabetes

U.S. Food and Drug Administration. (2023). 510(k) premarket notification. accessdata.fda.gov. Retrieved April 27, 2023, from https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K212835

U.S. Food and Drug Administration. (2017) De Novo Classification Request for Aquabeam System. Retrieved April 25, 2023, from https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN170024.pdf

Yale Medicine. (2022). Minimally invasive surgery. Yale Medicine. Retrieved May 3, 2023, from https://www.yalemedicine.org/conditions/minimally-invasive-surgery#:~:text=%E2%80%A2A%20type%20of%20surgery,as%20laparoscopic%20or%20keyhole%20procedures

VI. CDI History/Revision Information

- Explanation of changes to the CDI

Revision Type	Date of Revision	Update(s) Made to CDI
	MM/DD/YYYY	
	MM/DD/YYYY	