

Transurethral Waterjet Ablation of Prostate

Policy Number: 066

	Commercial and Qualified Health Plans	MassHealth	Medicare Advantage
Authorization Required	X		X
No Prior Authorization			
Not Covered		X	

Overview

The purpose of this document is to describe the guidelines Mass General Brigham Health Plan utilizes to determine the medical necessity for transurethral waterjet ablation (also referred to as robotic waterjet ablation or Aquablation) to treat lower urinary tract symptoms (LUTS) attributable to benign prostatic hyperplasia (BPH). The treating specialist must request prior authorization for the procedure.

Coverage Guidelines

The use of an FDA approved device (e.g., Aquabeam Robotic System) to treat BPH may be considered medically necessary for members less than or equal to 80 years of age when ALL of the following have been met:

1. The member has persistent moderate to severe symptoms LUTS despite maximal medical management including ALL of the following:
 - a. Failure, contraindication, or intolerance to at least three months of conventional medical therapy for LUTS/BPH such as alpha blockers, PDE5 inhibitors, and finasteride/dutasteride
 - b. International Prostate Symptom Score ≥ 12
 - c. Maximum urinary flow rate (Qmax) of ≤ 15 mL/s (voided volume greater than 125 cc)
2. The prostate gland volume is 30-150 cc by transrectal ultrasound (TRUS)

Exclusions

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

Medicare Variations

Mass General Brigham Health Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) for coverage determinations for its Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and documentation included in the Medicare manuals are the basis for coverage determinations. When there is no guidance from CMS for the

requested service, Mass General Brigham Health Plan’s medical policies are used for coverage determinations. At the time of Mass General Brigham Health Plan’s most recent policy review, Medicare includes coverage guidelines for the following:

- LCD: Fluid Jet System Treatment for LUTS/BPH (L38367)
- Local Coverage Article: Billing and Coding: Fluid Jet System Treatment for LUTS/BPH (A56797)

Definitions

Transurethral waterjet ablation: A minimally invasive procedure that uses a high-velocity water jet combined with real-time, imaging and robotics, to resect and remove a predetermined volume of prostatic tissue.

CPT/HCPC Codes

Authorized CPT/HCPCS Codes	Code Description
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

Effective

July 2023: Effective Date.

References

Desai M, Bidair M, Zorn KC, et al. Aquablation for benign prostatic hyperplasia in large prostates (80-150 mL): 6-month results from the WATER II trial. BJU International. 2019;08:08.

Desai M, Bidair M, Bhojani N, et al. Aquablation for benign prostatic hyperplasia in large prostates (80-150 cc): 2-year results. Can J Urol. 2020;27(2):10147-10153. PMID: 32333733.

FDA. FDA Approval: De Nova Classification Request for AQUABEAM System. https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN170024.pdf. Accessed 1/30/2023

Gilling, P., Barber, N., Bidair, M., et al. WATER: A double blind, randomized, controlled trial of Aquablation vs transurethral resection of the prostate in benign prostatic hyperplasia. J Urol. May 2018. 199(5). 1252-1261.

Gilling PJ, Barber N, Bidair M, et al. Randomized Controlled Trial of Aquablation versus Transurethral Resection of the Prostate in Benign Prostatic Hyperplasia: One-year Outcomes. Urology. 2019;125:169-173. 15.

Gilling P, Barber N, Bidair M, et al. Two-Year Outcomes After Aquablation Compared to TURP: Efficacy and Ejaculatory Improvements Sustained. 2019;36(6):1326-1336.

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.

Lerner LB, McVary, KT, Barry MJ et al: Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia: AUA Guideline part II, surgical evaluation and treatment . J Urol 2021; 206: 818

National Government Services, Inc. Local Coverage Determination (LCD): Fluid Jet System Treatment for LUTS/BPH (L38367). Revision Effective Date 11/01/2020. Available: [Medical Policies - NGSMEDICARE](#)

National Government Services, Inc. Local Coverage Article (LCA) Billing and Coding: Fluid Jet System Treatment for LUTs/BPH (A56797). Revision Effective Date 11/01/2020. Available: [Medical Policies - NGSMEDICARE](#)



Nguyen DD, Barber N, Bidair M, Gilling P. et al. WATER versus WATER II 2-Year Update: Comparing Aquablation Therapy for Benign Prostatic Hyperplasia in 30-80-cm³ and 80-150-cm³ Prostates. *Eur Urol Open Sci.* 2021 Jan 31;25:21-28. doi: 10.1016/j.euros.2021.01.004. PMID: 34337500; PMCID: PMC8317818.

Nickel JC, Aaron L, Barkin J, Elterman D, Nachabé M, Zorn KC. Canadian Urological Association guideline on male lower urinary tract symptoms/benign prostatic hyperplasia (MLUTS/BPH): 2018 update. *Can Urol Assoc J.* 2018 Oct;12(10):303-312. doi: 10.5489/cuaj.5616. PMID: 30332601; PMCID: PMC6192748.

