



## **Transurethral Waterjet Ablation of Prostate Clinical Coverage Criteria**

### **Overview**

Benign prostatic hyperplasia (BPH) is nearly ubiquitous in the aging male with increases in prevalence starting at age 40-45 years, reaching 60% by age 60, and 80% by age 80. BPH can lead to benign prostatic enlargement (BPE), which can cause obstruction at the level of the bladder neck, termed benign prostatic obstruction (BPO). Parallel to the development of BPH, lower urinary tract symptoms (LUTS) increase in frequency and severity with age and are divided into those associated with storage of urine, and/or voiding/emptying. Male LUTS may be caused by a variety of conditions, including BPE and BPO. BPH and LUTS in the aging male can be progressive, as seen in the Olmsted County Study (Sarma et al., 2003). The prevalence of moderate-to-severe LUTS rose to nearly 50% by age 80, with the development of acute urinary retention (AUR) increasing from an incidence of 6.8 episodes per 1,000 patient years of follow-up in the overall population, to a high of 34.7 episodes in men aged 70 and older (Lerner et al., 2021a).

The most important motivations for men seeking treatment are severity and degree of bother associated with symptoms (McVary, 2006). While LUTS/BPH is rarely life-threatening, the impact on quality of life is significant and should not be underestimated. The most prevalent and generally first line approach is behavioral and lifestyle modifications followed by medical therapy, including alpha-adrenergic antagonists (alpha blockers), 5-alpha reductase inhibitors (5ARIs), phosphodiesterase 5 selective inhibitors (PDE5s), anticholinergics, and beta-3 agonists - which may be utilized alone, or in combination to take advantage of their different mechanisms of action. Although effective treatments for LUTS/BPH are available, this condition often occurs in the context of common, age-related comorbidities such as cardiovascular disease, hypertension, and erectile dysfunction. When selecting an appropriate course of therapy, these side effects and any impact they may have on existing comorbid conditions must be considered (Lerner et al., 2021a).

When treatment with medications is not successful, surgical options may be considered. Simple prostatectomy and transurethral resection of the prostate (TURP) are the gold standard surgical treatments for LUTS attributed to BPH and are highly effective and provide improved outcomes in urinary functions. However, neither simple prostatectomy nor TURP are without perioperative complications and morbidity (Chung and Woo, 2018).

Recently, new minimally invasive surgeries have emerged as alternatives to prostatectomy and TURP for the management of LUTS in some men with BPH. These minimally invasive surgeries include but are not limited to:

- Transurethral waterjet ablation, (also referred to as robotic waterjet ablation or Aquablation)
- Prostatic Urethral Lift (PUL)
- Water Vapor Thermal Therapy
- Holmium laser enucleation of the prostate (HoLEP)

Promising short-term, results for minimally invasive alternatives have resulted in conditional or in some cases, moderate recommendations from the American Urological Association (AUA). By and large, factors that need to be taken into consideration when choosing a surgical option come

down to experience of the urologist, size of the prostate and desire to preserve sexual function (Lerner et al., 2021b).

Transurethral waterjet ablation, (also referred to as robotic waterjet ablation or Aquablation) uses high-pressure waterjet technology combined with real-time, imaging and robotics to resect and remove prostatic tissue. At this time, only one fluid jet system is approved by the FDA for the resection and removal of prostate tissue for the treatment of symptomatic BPH (510 (k) Product Code PZP). The Aquabeam Robotic System (Procept BioRobotics Corp., Redwood Shores, CA) was initially granted marketing authorization pursuant to a de novo classification (DEN170024 April 17, 2017) and subsequently granted 510(k) clearance on October 6, 2021 (K212835).

Promising short- and mid-term results for waterjet ablation (WATER) have resulted in a conditional recommendation from the American Urological Association (AUA) (Lerner et al., 2021). The conditional recommendation with Grade C evidence level translates to “Balance between benefits & risks/burdens unclear; Alternative strategies may be equally reasonable; Better evidence likely to change confidence,” echoing the Cochrane Review recommendation: “any recommendation for or against the use of Aquablation would be based on only very low-certainty evidence (Hwang et al., 2019).” In 2018, NICE issued the following guidance on transurethral water jet ablation for LUTS caused by BPH. “The evidence on transurethral water jet ablation for lower urinary tract symptoms caused by benign prostatic hyperplasia raises no major safety concerns. The evidence on efficacy is limited in quantity. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research (NICE 2018).”

Five-year outcomes from WATER (NCT02505919) demonstrate BPH symptom reduction and urinary flow rate improvement similar to TURP in men with prostate sizes between 30 and 80 cc. At 5-year follow-up, 6.0% of the intent-to-treat population in the Aquablation arm (7/116) needed an additional BPH therapy due to recurrent LUTS compared to 12.3% in the TURP arm (8/65), however, only 58/116 and 32/65 patients were available for follow-up after month 36 (Gilling et al., 2022). It is noteworthy that the AUA, Cochrane NICE recommendations predate the publication of five-year results for WATER (Gilling et al., 2022).

WATER II (NCT03123250) is single arm safety and effectiveness study of the waterjet ablation procedure for treatment with men (n=101) with symptomatic BPH and large volume 80-150 cc prostates. One and two-year results of WATER II are published by Bhojani et al., 2019 and Desai et al., 2020, respectively. Nguyen et al. 2020 compared the results of WATER and WATER II, and found an increase in complications and statistically significant but clinically unimportant differences in procedural times (3.9 minutes vs 8 minutes) and maintenance of antegrade ejaculation (90% vs 81%) between WATER and WATER II cohorts respectively.

One systematic review (Lebdai et al., 2018), assessed the loss of ejaculation and erectile dysfunction after surgical treatment for BPH, and concluded that Aquablation seems to be a reasonable option for those concerned with sexual dysfunction but also labelled the need for longer-term outcomes of procedure durability. The ejaculation preservation rate of prostatic urethral lift and Aquablation compared to TURP was 100 and 90 versus 34%, respectively.

## Policy

This Policy applies to the following Fallon Health products:

- ☒ Commercial
- ☒ Medicare Advantage
- ☒ MassHealth ACO
- ☒ NaviCare
- ☐ PACE

Fallon Health follows guidance from the Centers for Medicare and Medicaid Services (CMS) for organization (coverage) determinations for Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and guidance in the Medicare manuals are the basis for coverage determinations. When there is no NCD, LCD, LCA or manual guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations.

Medicare does not have an NCD for transurethral waterjet ablation of the prostate. National Government Services, Inc. is the Part A/B Medicare Administrative Contractor (MAC) with jurisdiction in our service area. National Government Services, Inc. has an LCD (L38367) and LCA (A56797) for transurethral waterjet ablation of the prostate. The National Government Services, Inc. LCD and LCA are titled Fluid Jet System Treatment for LUTS/BPH (MCD search 05/18/2022). Fluid jet system is the name of the device in the FDA regulation (876.4350).

For plan members enrolled in NaviCare, Fallon Health follows Medicare guidance for coverage determinations. Unless otherwise noted, in the event that there is no Medicare guidance or if the plan member does not meet medical necessity criteria in Medicare guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations for NaviCare members.

Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

Unless otherwise noted, Fallon Health Clinical Coverage Criteria are used to determine medical necessity for MassHealth ACO-covered services for MassHealth ACO members. Fallon Health Clinical Coverage Criteria are developed in accordance with the definition of Medical Necessity in 130 CMR 450.204 and therefore no more restrictive than MassHealth Medical Necessity guidelines.

## **Fallon Health Clinical Coverage Criteria**

### **Part I. Commercial and MassHealth**

Fallon Health considers transurethral waterjet ablation (0421T) for the treatment of symptomatic benign prostatic hyperplasia experimental/investigational. Claims for 0421T will deny vendor liable.

### **Part II. Medicare Advantage and NaviCare**

In accordance with Medicare regulatory requirements, transurethral waterjet ablation of prostate (0421T) is covered for Medicare Advantage and NaviCare plan members when coverage criteria in National Government Services, Inc. LCD Fluid Jet System Treatment for LUTS/BPH (L38367) and LCA Billing and Coding: Fluid Jet System Treatment for LUTs/BPH (A56797) are met.

Prior authorization is required.

#### Links

LCD: [Fluid Jet System Treatment for LUTS/BPH \(L38367\)](#)

LCA: [Billing and Coding: Fluid Jet System Treatment for LUTs/BPH \(A56797\)](#)

In accordance with National Government Services, Inc. LCD Fluid Jet System Treatment for LUTS/BPH (L38367), transurethral waterjet ablation for the treatment of lower urinary tract symptoms (LUTS) attributable to benign prostatic hyperplasia (BPH) is considered medically necessary when performed once in Medicare Advantage and NaviCare members who meet all of the following criteria:

1. Age  $\leq$ 80

2. Prostate volume of 30-150 cc by transrectal ultrasound (TRUS)
3. Persistent moderate to severe symptoms despite maximal medical management including ALL of the following:
  - a. International Prostate Symptom Score (IPSS)  $\geq 12$
  - b. Maximum urinary flow rate (Qmax) of  $\leq 15$  mL/s (voided volume greater than 125 cc)
  - c. Failure, contraindication or intolerance to at least three months of conventional medical therapy for LUTS/BPH (e.g., alpha blocker, PDE5 Inhibitor, finasteride/dutasteride)

Only treatment using a device that is FDA approved/cleared for waterjet resection and removal of prostate tissue is considered medically necessary.

Transurethral waterjet ablation of prostate is considered not medically necessary for plan members with any of the following:

- Body mass index  $\geq 42$  kg/m<sup>2</sup>
- 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.
- Bladder cancer, neurogenic bladder, bladder calculus or clinically significant bladder diverticulum
- Active urinary tract or systemic infection
- Treatment for chronic prostatitis
- Diagnosis of urethral stricture, meatal stenosis, or bladder neck contracture
- Damaged external urinary sphincter
- Known allergy to device materials
- Inability to safely stop anticoagulants or antiplatelet agents preoperatively

## Exclusions

- Transurethral waterjet ablation of prostate (0421T) is considered experimental/investigational for commercial and MassHealth plan members.

## Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

HCPCS C2596 is specific to the probe used in image-guided, robotic, waterjet ablation. C2596 has pass-through status effective 1/1/2020 through 12/31/2022 (reimbursed at "reasonable cost"). Pass-through status for C2596 applies to OPPS and ASC settings. Beginning 1/1/2023, pass-through status is expired and C2596 will not be reimbursed separately under OPPS or ASC reimbursement methodology.

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

ICD-10-CM	Description
N40.1	Benign prostatic hyperplasia with lower urinary tract symptoms

## References

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## Policy history

Origination date: 06/01/2022  
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*Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.*