

Medical Coverage Policy | Transurethral Water Jet Ablation (Aquablation) for Benign Prostatic Hypertrophy



EFFECTIVE DATE: 05|01|2023

POLICY LAST UPDATED: 01|04|2023

OVERVIEW

Transurethral waterjet ablation (aquablation) has been investigated as minimally invasive alternatives to transurethral resection of the prostate (TURP), considered the traditional standard treatment for benign prostatic hyperplasia (BPH). Aquablation cuts tissue by using a pressurized jet of fluid delivered to the prostatic urethra.

Note: This policy is applicable for Commercial Products only. For Medicare Advantage Plans, see the applicable policy in the Related Policies section.

MEDICAL CRITERIA

Commercial Products

Treatment for lower urinary tract symptoms/benign prostatic hyperplasia (LUTS/BPH) using fluid jet system treatment (may also be known as Aquablation) will be considered reasonable and necessary when performed ONCE in individuals that meet the following (1, 2 and 3):

1. Indications including ALL of the following:

- a. Age \leq 80 AND
- b. Prostate volume of 30-150 cc by transrectal ultrasound (TRUS) AND
- c. Persistent moderate to severe symptoms despite maximal medical management including ALL of the following:
 - i. International Prostate Symptom Score (IPSS) \geq 12 AND
 - ii. Maximum urinary flow rate (Q_{max}) of \leq 15 mL/s (voided volume greater than 125 cc) AND
 - 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)

AND

2. Only treatment using an FDA approved/cleared device will be considered reasonable and necessary.

AND

3. The individual must not have ANY of the following:

- a. Body mass index \geq 42kg/m²
- b. 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.
- c. Bladder cancer, neurogenic bladder, bladder calculus or clinically significant bladder diverticulum
- d. Active urinary tract or systemic infection
- e. Treatment for chronic prostatitis
- f. Diagnosis of urethral stricture, meatal stenosis, or bladder neck contracture
- g. Damaged external urinary sphincter
- h. Known allergy to device materials
- i. Inability to safely stop anticoagulants or antiplatelet agents preoperatively.

PRIOR AUTHORIZATION

Commercial Products

Prior Authorization is recommended for transurethral waterjet ablation (aquablation) for Commercial Products.

POLICY STATEMENT

Commercial Products

Treatment for lower urinary tract symptoms/benign prostatic hyperplasia (LUTS/BPH) using fluid jet system treatment (may also be known as Aquablation) will be considered medically necessary when the criteria above has been met.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/coverage or surgery benefit.

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 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 the 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.

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). TURP 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.

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). The device is intended for the resection and removal of prostate tissue in males suffering from LUTS due to BPH.

CODING

Commercial Products

The following CPT code(s) is medically necessary when the medical criteria above has been met:

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)

RELATED POLICIES

Prior Authorization via Web-Based Tool for Procedures

Prostatic Urethral Lift

Transurethral Water Jet Ablation (Aquablation) for Benign Prostatic Hypertrophy

PUBLISHED

Provider Update, March 2023
Provider Update, September 2022
Provider Update, August 2021
Provider Update, July 2020
Provider Update, November 2019

REFERENCES

1. UpToDate. Medical treatment of benign prostatic hyperplasia. 2022. Available at: https://www.uptodate.com/contents/medical-treatment-of-benign-prostatic-hyperplasia?search=benign%20prostatic%20hyperplasia&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1. Accessed April 22, 2022.
2. Westwood J, Geraghty R, Jones P, et al. Rezum: a new transurethral water vapour therapy for benign prostatic hyperplasia. *Ther Adv Urol*. Nov 2018; 10(11): 327-333. PMID 30344644
3. McVary KT, Roehrborn CG. Three-Year Outcomes of the Prospective, Randomized Controlled Rezum System Study: Convective Radiofrequency Thermal Therapy for Treatment of Lower Urinary Tract Symptoms Due to Benign Prostatic Hyperplasia. *Urology*. Jan 2018; 111: 1-9. PMID 29122620
4. Food and Drug Administration (2017). Aquabeam System Device Classification Under Section 513(f)(2)(De Novo). <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm?ID=DEN170024>. Accessed April 22, 2022.
5. Kang TW, Jung JH, Hwang EC, et al. Convective radiofrequency water vapour thermal therapy for lower urinary tract symptoms in men with benign prostatic hyperplasia. *Cochrane Database Syst Rev*. Mar 25 2020; 3: CD013251. PMID 32212174
6. 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
7. 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*. Mar 2019; 125: 169-173. PMID 30552937
8. Gilling P, Barber N, Bidair M, et al. Three-year outcomes after Aquablation therapy compared to TURP: results from a blinded randomized trial. *Can J Urol*. Feb 2020; 27(1): 10072-10079. PMID 32065861
9. Hwang EC, Jung JH, Borofsky M, et al. Aquablation of the prostate for the treatment of lower urinary tract symptoms in men with benign prostatic hyperplasia. *Cochrane Database Syst Rev*. Feb 13 2019; 2: CD013143. PMID 30759311
10. 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*. Oct 2021; 206(4): 818-826. PMID 34384236
11. 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>. Accessed April 23, 2022.

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