KAISER PERMANENTE® Mid-Atlantic States	**Transurethral Water Jet Ablation (Aquablation) for Benign Prostatic Hypertrophy Medical Coverage Policy**

UTILIZATION * ALERT*

- Prior to use of this MCP for evaluation of medical necessity, benefit coverage MUST be verified in the member's EOC or benefit document.
- Please refer to CMS guidelines or Medicare Coverage Database for Medicare members.

I. Procedure: **Transurethral Water Jet Ablation (Aquablation)**

II. Diagnosis: Benign Prostatic Hypertrophy

III. **Clinical Indications for Referral**

Transurethral water jet ablation (Aquablation**)** is considered medically necessary once per lifetime for the treatment of lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH) when **ALL** of the following criteria are met:

A. Prostate volume is between 30-150 cc via transrectal ultrasound; **and**

B. Persistent moderate to severe symptoms despite maximal medical management including the following:
   1. Maximum urinary flow rate (Qmax) of ≤15 mL/s[4] (voided volume greater than 125 cc); **OR**
   2. International Prostate Symptom Score (IPSS) ≥12; **and**

C. Contraindicated, intolerance or failure to at least three months of conservative medical treatment for LUTS/BPH (Alpha-1-receptor antagonists, 5-Alphareductase Inhibitors, or Anticholinergics).

IV. Contraindication and Limitation

A. Contraindication

Transurethral waterjet ablation of the prostate is contraindicated in patients with **any** of the following:

1. Active urinary tract or systemic infection; or
2. Known allergy to device materials; or
3. Inability to safely stop anticoagulants or antiplatelet agents preoperatively; or
4. Known or suspected prostate cancer or a prostate specific antigen (PSA) >10 ng/mL unless there was a negative prostate biopsy within the last 6 months.

B. Limitation

Transurethral waterjet ablation of the prostate is not medically necessary in the presence of **any** of the following:

1. Body mass index ≥ 42kg/m^2; **or**

2. Bladder cancer, bladder calculus, neurogenic bladder, or clinically significant bladder diverticulum; **or**
3. Diagnosis of urethral stricture, meatal stenosis, or bladder neck contracture; **or**
4. Damaged external urinary sphincter**; or**
5. Treatment for chronic prostatitis

V. Risks

The following are potential risks from operation of the aquablation device:

A. Bleeding;
B. Bruising;
C. Bladder or prostate capsule perforation;
D. Dysuria;
E. Embolism;
F. Electromagnetic interference or electrical shock;
G. Failure to remove target tissue or non-target tissue removal;
H. Rectal incontinence or perforation;
I. Sexual dysfunction including erectile and ejaculatory dysfunction;
J. Transurethral resection syndrome;
K. Urethral damage causing false passage or stricture;
L. Incontinence;
M. Infection; and
N. Pelvic or penile pain

VI. Description

AquaBeam Robotic System (Aquablation) manufactured by PROCEPT BioRobotics, is a class II (special controls) fluid jet system device which is intended for the resection and removal of prostate tissue in males who suffer from lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia. The robotic system was cleared by the FDA in December 2017.

Fluid jet system for prostate tissue removal is a device for treating benign prostatic hyperplasia by resecting and removing prostatic tissue through a pressurized jet of fluid to the prostatic urethra.

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Approval History

Effective June 01, 2016, state filing is no longer required per Maryland House Bill HB 798 – Health Insurance – Reporting

Date approved by RUMC	Date of Implementation
05/23/2024	05/23/2024

*The Regional Utilization Management Committee received delegated authority in 2011 to review and approve designated Utilization Management and Medical Coverage Policies by the Regional Quality Improvement Committee.

Note: Kaiser Permanente Mid-Atlantic States (KPMAS) include referral and authorization criteria to support primary care and specialty care practitioners, as appropriate, in caring for members with selected conditions. Medical Coverage Policies are not intended or designed as a substitute for the reasonable exercise of independent clinical judgment by a practitioner in any particular set of circumstances for an individual member.