

MEDICAL POLICY

POLICY TITLE	TRANSURETHRAL WATER VAPOR THERMAL THERAPY AND TRANSURETHRAL WATER JET ABLATION (AQUABLATION) FOR BENIGN PROSTATIC HYPERTROPHY
POLICY NUMBER	MP 4.053

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☐ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective date:	10/1/2026

POLICY

Transurethral water vapor thermal therapy is considered **investigational** as a treatment of benign prostatic hyperplasia. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Transurethral waterjet ablation (aquablation) is considered **investigational** as a treatment of benign prostatic hyperplasia. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-References:

MP 1.147 Prostatic Urethral Lift

MP 1.164 Temporarily Implanted Nitinol Device (iTind) for Benign Prostatic Hyperplasia

MP 4.043 Focal Treatments for Prostate Cancer

MP 4.054 Hydrogel Spacer use During Radiotherapy for Prostate Cancer

MP 5.053 Magnetic Resonance–Guided Focused Ultrasound

PRODUCT VARIATIONS

This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: <https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies>.

DESCRIPTION/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 years and older. 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

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POLICY NUMBER	MP 4.053

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 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). Transurethral resection of the prostate 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.

Transurethral water vapor thermal therapy and aquablation have been investigated as minimally invasive alternatives to TURP. Transurethral water vapor thermal therapy uses radiofrequency-generated water vapor (~103°C) thermal energy based on the thermodynamic properties of convective versus conductive heat transfer to ablate prostate tissue. Aquablation cuts tissue by using a pressurized jet of fluid delivered to the prostatic urethra.

Regulatory Status

In September 2016, the Rezum™ System (NxThera, Inc, acquired by Boston Scientific in 2018) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process (K150786). The FDA determined that this device was substantially equivalent to existing devices (Medtronic Prostiva devices). Rezum is intended to relieve symptoms, obstructions, and reduce prostate tissue associated with BPH. It is indicated for men >50 years of age with a prostate volume >30 cm³ and <80 cm³. The Rezum System is also indicated for the treatment of prostate with hyperplasia of the central zone and/or a median lobe.

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 with LUTS due to BPH, based on WATER trial.

MEDICAL POLICY

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POLICY NUMBER	MP 4.053

RATIONALE

Summary of Evidence

For individuals who have benign prostatic hypertrophy (BPH) and lower urinary tract symptoms (LUTS) who receive transurethral water vapor thermal therapy, the evidence includes a single 3-month, sham-controlled, randomized trial of 197 patients with a 5-year uncontrolled follow-up phase and 1 multicenter, prospective, single-arm study. The outcomes of interest are symptoms, functional outcomes, quality of life, and treatment-related morbidity. At 3 months, LUTS improved more in the intervention group compared to the sham procedure. No adverse effects on erectile or ejaculatory function were observed, and improvements were sustained through 5 years of follow-up. The evidence is limited by the small sample size, lack of blinding of longer-term outcomes, and lack of comparison to alternative treatments such as transurethral resection of the prostate (TURP). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have BPH and LUTS who receive aquablation, the evidence includes a single noninferiority randomized controlled trial (RCT) of aquablation compared to TURP in 187 patients with 5 years of follow-up, and several multicenter, prospective, single-arm studies. The outcomes of interest are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The primary efficacy endpoint in the RCT was the difference between groups in the change in International Prostate Symptom Score (IPSS) at 6 months, and the primary safety endpoint was the development of Clavien-Dindo persistent grade 1, or 2 or higher operative complications at 3 months. At 6 months, mean IPSS decreased from baseline by 16.9 points for aquablation and 15.1 points for TURP (mean difference, 1.8 points; $p < .0001$ for noninferiority and $p = .1347$ for superiority). The primary safety endpoint rate was lower in the aquablation group compared to the TURP group (26% vs. 42%; $p = .0149$). The rate of grade 2 and greater events was similar in the 2 groups (20% for aquablation and 23% for TURP; $p = .3038$). Over 5 years, improvements remained similar between groups with no new safety signals. Confidence in these conclusions is reduced due to imprecision of estimates and a lack of additional supportive trials, especially with regard to comparative adverse events. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

DEFINITIONS

N/A

DISCLAIMER

Capital Blue Cross' medical policies are used to determine coverage for specific medical technologies, procedures, equipment, and services. These medical policies do not constitute medical advice and are subject to change as permitted by law or applicable clinical evidence from independent treatment guidelines. Treating providers are solely responsible for medical advice and treatment of members. These policies are not a guarantee of coverage or

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payment. Payment of claims is subject to a determination regarding the member's benefit program and eligibility on the date of service, and a determination that the services are medically necessary and appropriate. Final processing of a claim is based upon the terms of contract that applies to the members' benefit program, including benefit limitations and exclusions. If a provider or a member has a question concerning this medical policy, please contact Capital Blue Cross' Provider Services or Member Services.

CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational for Benign Prostatic Hypertrophy

Procedure Codes							
C2596	52597	53854	55899				

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POLICY NUMBER	MP 4.053

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MEDICAL POLICY

POLICY TITLE	TRANSURETHRAL WATER VAPOR THERMAL THERAPY AND TRANSURETHRAL WATER JET ABLATION (AQUABLATION) FOR BENIGN PROSTATIC HYPERTROPHY
POLICY NUMBER	MP 4.053

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POLICY HISTORY

MP 4.053	04/01/2026 Major Review; creation of new policy. Statements removed from MP 4.043

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