Transurethral Water Vapor Thermal Therapy and Transurethral Water Jet Ablation (Aquablation) for Benign Prostatic Hypertrophy

Policy # 00684
Original Effective Date: 12/01/2019
Current Effective Date: 12/12/2022

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member’s contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider water vapor energy ablation (Rezum) for the treatment of benign prostatic hyperplasia (BPH) to be eligible for coverage when ALL of the following criteria are met:

Patient Selection Criteria

Coverage eligibility will be considered when all of the following criteria are met:

- Moderate to severe lower urinary tract symptoms; AND
- > 50 years of age; AND
- Failure or inability to tolerate medical therapy (α1-adrenergic antagonists maximally titrated, 5α-reductase inhibitors, or combination medication therapy maximally titrated) over a trial period of no less than 6 months; AND
- Prostate volume < 80 (g) cm³; AND
- Appropriate testing to exclude diagnosis of prostate cancer has been completed; AND
- No contraindications to the procedure, including urinary retention, urinary tract infection, or recent prostatitis within the past year.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.
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Based on review of available data, water vapor energy ablation (Rezum) for all other indications, including but not limited to use in patients with a diagnosis of prostate cancer, use after other minimally invasive procedures for BPH (e.g. prostatic urethral lift), and repeat use of transurethral water vapor thermal therapy is considered to be investigational.*

Based on review of available data, Transurethral waterjet ablation (aquablation) as a treatment of benign prostatic hyperplasia is considered to be investigational.*

Background/Overview
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. BPH 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 including urinary frequency, urgency, irregular flow, weak stream, straining, and waking up at night to urinate. Lower urinary tract symptoms is the most commonly presenting urological complaint and can have a significant impact on the quality of life.

BPH 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 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
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involves the insertion of one 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 transurethral resection of the prostate. Transurethral water vapor thermal therapy uses radiofrequency-generated water vapor (~103°C) thermal energy based on the thermodynamic properties of convective vs conductive heat transfer to ablate prostate tissue. Aquablation cuts tissue by using a pressurized jet of fluid delivered to the prostatic urethra.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
In September 2016, the Rezum™ System (NxThera, Inc, acquired by Boston Scientific in 2018) was cleared for marketing by the U.S. 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 benign prostatic hyperplasia. It is indicated for men > 50 years of age with a prostate volume >30cm³ and <80cm³. 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 suffering from LUTS due to benign prostatic hyperplasia.

Rationale/Source
This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. FDA approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.
Supplemental Information

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Urological Association

In 2021, the American Urological Association published guidelines on the surgical evaluation and treatment of lower urinary tract symptoms (LUTS) attributed to benign prostatic hyperplasia (BPH) and included the following recommendations related to the interventions included in this evidence review:

- Water vapor thermal therapy should be considered as a treatment option for patients with LUTS/BPH provided prostate volume is 30 to 80 cc. (Moderate Recommendation; Evidence Level: Grade C)
- Water vapor thermal therapy may be offered as a treatment option to eligible patients who desire preservation of erectile and ejaculatory function. (Conditional Recommendation; Evidence Level: Grade C)
- Robotic waterjet treatment may be offered as a treatment option to patients with LUTS/BPH provided prostate volume is 30 to 80 cc. (Conditional Recommendation; Evidence Level: Grade C)

National Institute for Health and Care Excellence

In 2020, the National Institute for Health and Care Excellence (NICE) issued the following guidance on Rezum for treatment of LUTS secondary to BPH:

"Evidence supports the case for adopting Rezum for treating lower urinary tract symptoms (LUTS) caused by benign prostatic hyperplasia (BPH) in the NHS. Rezum relieves LUTS and improves quality of life."
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"Rezum is a minimally invasive procedure. It should be considered as a treatment option for people with:

- moderate to severe LUTS (International Prostate Symptoms Score [IPSS] typically 13 or over) and
- a moderately enlarged prostate (typically between 30 cm³ and 80 cm³)."

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."

The guidance also states, "NICE encourages further research into transurethral water jet ablation for LUTS caused by BPH and may update the guidance on publication of further evidence. Further research should report long-term follow-up and include reintervention rates."

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Ongoing trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

<table>
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<th>NCT No.</th>
<th>Trial Name</th>
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<th>Completion Date</th>
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<tr>
<th>NCT04338776a</th>
<th>C.L.E.A.R. - Comparing UroLift Experience Against Rezum</th>
<th>120</th>
<th>Dec 2023</th>
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<tr>
<td>NCT04801381</td>
<td>WATER III: A Randomized, Controlled Trial of Aquablation vs. Transurethral Laser Enucleation of Large Prostates (80 - 180 mL) in Benign Prostatic Hyperplasia</td>
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<td>Dec 2027</td>
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aNDenotes industry sponsored or cosponsored trial
NCT: National Clinical Trial

References

Policy History
Original Effective Date: 12/01/2019
Current Effective Date: 12/12/2022
09/05/2019 Medical Policy Committee review
11/05/2020 Medical Policy Committee review
11/04/2021 Medical Policy Committee review
11/10/2021 Medical Policy Implementation Committee approval. Title changed. Added “Based on review of available data, Transurethral waterjet ablation (aquablation) as a treatment of benign prostatic hyperplasia is considered to be investigational.”
11/03/2022 Medical Policy Committee review
11/09/2022 Medical Policy Implementation Committee approval. No change to coverage.
Next Scheduled Review Date: 11/2023

Coding
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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

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<td>ICD-10 Diagnosis</td>
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</table>

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:
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A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
   1. Consultation with technology evaluation center(s);
   2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
   3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.
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NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.