Transurethral Water Vapor Thermal Therapy for Benign Prostatic Hyperplasia

Policy # 00684
Original Effective Date: 12/01/2019
Current Effective Date: 12/14/2020

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) cm^3; **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.

Transurethral Water Vapor Thermal Therapy for Benign Prostatic Hyperplasia

Policy # 00684
Original Effective Date: 12/01/2019
Current Effective Date: 12/14/2020

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.***

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.
Transurethral water vapor thermal therapy has been investigated as a minimally invasive alternative to transurethral resection of the prostate. The procedure uses radiofrequency-generated water vapor (~103°C) thermal energy to ablate prostate tissue.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In September 2016, the Rezum System™‡ (NxThera, Inc) 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 >30cm^3 and <80cm^3. The Rezum System is also indicated for the treatment of prostate with hyperplasia of the central zone and/or a median lobe.

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, Blue Cross and Blue Shield Association technology assessment program (TEC) and other non-affiliated technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Supplemental Information

Practice Guidelines and Position Statements

American Urological Association

The American Urological Association (2018) issued clinical practice guidelines on benign prostatic hyperplasia (amended 2019) and made the following recommendations for water vapor thermal therapy:

- Water vapor thermal therapy may be offered to patients with lower urinary tract symptoms attributed to benign prostatic hyperplasia provided prostate volume <80 g; however, patients should be counseled regarding efficacy and retreatment rates. (Conditional Recommendation; Evidence Level: Grade C)
- Water vapor thermal therapy may be offered to eligible patients who desire preservation of erectile and ejaculatory function. (Conditional Recommendation; Evidence Level: Grade C)

The recommendations were based on results of the randomized controlled trial conducted by McVary et al. (2015, 2018), and this body of evidence was considered low strength, leading to a conditional recommendation (Grade C).

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.

National Institute for Health and Care Excellence (NICE) 2020

1 Recommendations

1.1 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.

1.2 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).

1.3 Cost modelling estimates that Rezum is cost saving compared with standard treatments such as transurethral resection of the prostate (TURP) and holmium laser enucleation of the prostate (HoLEP) by more than £550 per person over 4 years. Savings compared with UroLift are uncertain. This is because of uncertainty about some of the assumptions in the cost modelling for that comparison.

In conclusion, the evidence demonstrates that Rezum is clinically effective and, as a minimally invasive procedure, it has benefits over other interventions that are likely to be valued by some men. In most scenarios, Rezum is likely to be significantly cost-saving, although this needs to be considered in the context of a lack of evidence comparing the clinical efficacy and durability of Rezum with more invasive surgical options.

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

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03605745[a]	Minimally Invasive Prostatic Vapor Ablation- Multicenter, Single-Arm Study for the Treatment of BPH in Large Prostates(Rezūm XL)	88	Mar 2023
NCT04338776[a]	C.L.E.A.R. - Comparing UroLift Experience Against Rezum	120	Jan 2022
Unpublished			
NCT02940392[a]	Rezum First in Man Feasibility Study for the Treatment of BPH With the Rezum System	15	Jun 2018 (completed)
NCT02943070[a]	NxThera Benign Prostatic Hyperplasia Rezum System Pilot Study	50	Dec 2018 (completed)

[a]Denotes industry sponsored or cosponsored trial
NCT: National Clinical Trial

References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "Transurethral Water Vapor Thermal Therapy for Benign Prostatic Hyperplasia", Policy 2.01.49, July 2020.
2. National Institute for Health and Care Excellence. Rezum for treating lower uninary tract symptoms secondary to benign prostatic hyperplasia. June 2020.

Policy History

Original Effective Date: 12/01/2019
Current Effective Date: 12/14/2020
09/05/2019 Medical Policy Committee review

Transurethral Water Vapor Thermal Therapy for Benign Prostatic Hyperplasia

Policy # 00684
Original Effective Date: 12/01/2019
Current Effective Date: 12/14/2020

09/11/2019 Medical Policy Implementation Committee approval. New policy.
11/05/2020 Medical Policy Committee review
11/11/2020 Medical Policy Implementation Committee approval. Coverage changed from investigational to eligible for coverage.
Next Scheduled Review Date: 11/2021

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2019 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

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:

Code Type	Code
CPT	53854, 55899

HCPCS	Code added eff 1/1/2020: C2596
ICD-10 Diagnosis	N40.0-N40.1

*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:

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 the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated 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.

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.