BlueCross BlueShield Federal Employee Program.

# FEP Medical Policy Manual

## FEP 2.01.49 Transurethral Water Vapor Thermal Therapy and Transurethral Water Jet Ablation (Aquablation) for Benign Prostatic Hypertrophy

### Effective Policy Date: October 1, 2021

### Original Policy Date: July 1, 2020

### Related Policies:

7.01.151 - Prostatic Urethral Lift

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

## Description

## Description

Transurethral water vapor thermal therapy and transurethral waterjet ablation (aquablation) have been investigated as minimally invasive alternatives to transurethral resection of the prostate, considered the traditional standard treatment for benign prostatic hyperplasia. Transurethral water vapor thermal therapy uses radiofrequency-generated water vapor (~103C) 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.

## OBJECTIVE

The objective of this evidence review is to determine if transurethral water vapor thermal therapy and aquablation improve the net health outcome in patients with benign prostatic hyperplasia and lower urinary tract symptoms.

# POLICY STATEMENT

Transurethral water vapor thermal therapy is considered **investigational** as a treatment of benign prostatic hyperplasia.

Transurethral waterjet ablation (aquablation) is considered **investigational** as a treatment of benign prostatic hyperplasia.

# POLICY GUIDELINES

None

# BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

# FDA 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 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.

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).[4.] The device is intended for the resection and removal of prostate tissue in males suffering from LUTS due to benign prostatic hyperplasia.

# RATIONALE

## Summary of Evidence

For individuals who have benign prostatic hyperplasia and lower urinary tract symptoms who receive transurethral water vapor thermal therapy, the evidence includes one 3-month, sham-controlled randomized controlled trial (RCT) of 197 patients with a 5-year uncontrolled follow-up phase. The outcomes of interest are symptoms, quality of life, and treatment-related morbidity. At three months, lower urinary tract symptoms 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, short-term duration, 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 benign prostatic hyperplasia and lower urinary tract symptoms who receive aquablation, the evidence includes one noninferiority RCT of aquablation compared to TURP in 187 patients with 3 years of follow-up. The outcomes of interest are symptoms, quality of life, and treatment-related morbidity. The primary efficacy endpoint was the difference between groups in the change in International Prostate Symptom Score (IPSS) at 6 months, and the primary safety end point was the development of Clavien-Dindo persistent grade 1, or 2 or higher operative complications at 3 months. At 6 months, mean I-PSS 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 3 years, improvements remained similar between groups. 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.

# 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

The American Urological Association (2018, amended 2019, 2020) issued clinical practice guidelines on benign prostatic hyperplasia (amended 2019) and made the following relevant recommendations:[13,]:

- Water vapor thermal therapy may be offered to patients with lower urinary tract symptoms attributed to benign prostatic hyperplasia provided prostate volume <80 g (Moderate 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)
- Aquablation may be offered to patients with LUTS attributed to BPH provided prostate volume >30/<80g. (Conditional Recommendation; Evidence Level: Grade C).
- Clinicians should inform patients of the possibility of treatment failure and the need for additional or secondary treatments when considering surgical and minimally-invasive treatments for LUTS secondary to BPH. (Clinical Principle).

### 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:[14,]

"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."

"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 $cm^3$ and 80 $cm^3$)."

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. "[15,]

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."[15,]

## 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.

# REFERENCES


1. UpToDate. Medical treatment of benign prostatic hyperplasia. 2019. 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 May 18, 2020.
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 May 27, 2021.
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. McVary KT, Gange SN, Gittelman MC, et al. Minimally Invasive Prostate Convective Water Vapor Energy Ablation: A Multicenter, Randomized, Controlled Study for the Treatment of Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia. J Urol. May 2016; 195(5): 1529-1538. PMID 26614889
7. McVary KT, Rogers T, Roehrborn CG. Rezum Water Vapor Thermal Therapy for Lower Urinary Tract Symptoms Associated With Benign Prostatic Hyperplasia: 4-Year Results From Randomized Controlled Study. Urology. Apr 2019; 126: 171-179. PMID 30677455
8. McVary KT, Gittelman MC, Goldberg KA, et al. Final 5-Year Outcomes of the Multicenter Randomized Sham-Controlled Trial of a Water Vapor Thermal Therapy for Treatment of Moderate to Severe Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia. J Urol. Apr 19 2021: 101097JU0000000000001778. PMID 33872051
9. 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
10. 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
11. 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
12. 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
13. American Urological Association Benign Prostatic Hyperplasia: Surgical Management of Benign Prostatic Hyperplasia/Lower Urinary Tract Symptoms, 2018 (amended 2019, 2020) Available at: https://www.auanet.org/guidelines/benign-prostatic-hyperplasia-(bph)-guideline. Accessed July 19, 2021.
14. 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 May 27, 2021.
15. National Institute for Health and Care Excellence (2018). Transurethral water jet ablation for lower urinary tract symptoms caused by benign prostatic hyperplasia. https://www.nice.org.uk/guidance/ipg629/chapter/1-Recommendations. Accessed May 26, 2021.

## POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

| Date | Action | Description |
|---|---|---|
| June 2020 | New policy | New Policy. Transurethral water vapor thermal therapy is investigational for BPH. |
| September 2020 | Replace policy | Policy updated with literature review through May 14, 2020; references added. Policy statement unchanged. |
| September 2021 | Replace policy | Policy updated with literature review through May 13, 2021; references added. New indication and investigational policy statement added for aquablation. Title changed to reflect new indication. Policy statement for transurethral water vapor thermal therapy unchanged. |