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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, 2023

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

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Transurethral water vapor thermal therapy and transurethral waterjet ablation (aquablation) have been investigated as minimally invasive alternatives to transurethral resection of the prostate (TURP), considered the traditional standard treatment for benign prostatic hyperplasia (BPH). 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 individuals with benign prostatic hyperplasia and lower urinary tract symptoms.

POLICY STATEMENT

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

Transurethral waterjet ablation (aquablation) is considered **medically necessary** 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 BPH. It is indicated for men >50 years of age with a prostate volume >30 cm^3 and <80 cm^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 with LUTS due to BP, based on WATER trial.

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.

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:[19,]

- Water vapor thermal therapy should be considered as a treatment option for patients with LUTS/BPH provided prostate volume is 30 to 80 mL. (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 mL. (Conditional Recommendation; Evidence Level: Grade C)

National Institute for Health and Care Excellence

In 2020, the NICE issued the following guidance on Rezum for treatment of LUTS secondary to BPH:[20,]

"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."[21,]

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."[21,]

A Medtech innovation briefing was released by NICE in January 2023 but guidance specific to Aquablation is awaiting development as of March 7, 2023.[22,]

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.

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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.
September 2022	Replace policy	Policy updated with literature review through April 21, 2022; references added. Policy statement for Water Vapor Thermal Therapy and Jet Ablation changed to medically necessary.
September 2023	Replace policy	Policy updated with literature review through May 1, 2023; references added. Policy statements unchanged.