**Transurethral Water Vapor Thermal Therapy of the Prostate**

Effective: April 1, 2019

**Next Review:** December 2019

**Last Review:** December 2018

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**IMPORTANT REMINDER**

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

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**DESCRIPTION**

Transurethral water vapor thermal therapy is a minimally invasive surgical therapy for the treatment of benign prostatic hypertrophy.

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**MEDICAL POLICY CRITERIA**

Transurethral water vapor thermal therapy of the prostate is considered **investigational**.

*NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.*

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**CROSS REFERENCES**

None

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**BACKGROUND**

Benign prostatic hyperplasia (BPH) is a diagnosis that describes the enlargement of the prostate often associated with a group of obstructive symptoms, termed lower urinary tract symptoms (LUTS). These symptoms include decreased force of stream, hesitancy, straining, incomplete bladder emptying, and nocturia. The enlargement is caused by the proliferation of epithelial and smooth muscle cells in the transition zone of the prostate. Proliferation generally
increases with age, and the initiation of BPH likely begins by the age of 30.[1] According to a multinational survey, 90% of men ages 50-80 experience BPH, although only 11% of men in the study received medical treatment.[2]

Standard management of BPH includes watchful waiting (active surveillance) in patients not bothered by their symptoms, medical management, surgery, and a number of new minimally invasive therapies. Surgical treatments include transurethral resection of the prostate (TURP), transurethral vaporization, holmium laser enucleation or resection of the prostate, prostatic artery embolization, and prostatectomy. Minimally invasive therapies include transurethral needle ablation of the prostate (TUNA) and transurethral microwave thermotherapy (TUMT), as well as transurethral water vapor thermal therapy.

Transurethral water vapor thermal therapy is a process by which water vapor is created outside of the body and delivered to the prostate with a needle. The treatment is repeated in multiple locations within the prostate. During the procedure, saline irrigation cools and protects the surface of the urethra. The heat from the vapor disrupts cell membranes in the prostate, which leads to cell death and necrosis.

REGULATORY STATUS

In 2015, the U.S. Food and Drug Administration (FDA) approved the Rezūm System® (NxThera, Inc.) under the 510(k) process for use in relieving symptoms and obstructions, and reducing prostate tissue associated with BPH.

EVIDENCE SUMMARY

The primary beneficial outcomes of interest are symptom reduction, measured in various ways, including the International Prostate Symptom Score (IPSS), the benign prostatic impact index (BPHII), and the maximum urinary flow rate (Qmax). Evaluating the safety and effectiveness of transurethral water vapor thermal therapy requires randomized comparisons with standard care. These comparisons are necessary to determine whether the benefits of implantable cardiac monitors outweigh any risks and whether they offer advantages over conventional methods with respect to increasing quality of life and decreasing symptoms.

Randomized Controlled Trials

A single randomized controlled trial (RCT) was identified, with results published in four publications.[3-6] One-hundred and ninety-seven men experiencing lower urinary tract symptoms associated with benign prostatic hyperplasia were randomized 2:1 to active water vapor ablation therapy with the Rezūm® System or a control procedure including rigid cystoscopy with simulated active treatment sounds. After three months, 53 of 61 control subjects who met criteria elected to participate in a crossover active treatment study. The International Prostate Symptom Score (IPSS) was 10.8 (standard deviation [SD] = 6.5) and 17.5 (SD = 7.6) in the active therapy and sham groups, respectively (p<0.0001) at three months post-treatment. The peak flow-rate (Qmax) increased significantly more in the treatment group at three months, to 16.1 (SD =7.3), compared with 10.8 (SD = 4) in the sham group (p<0.0001). Quality of life, as measured by the IPSS-QOL question, was statistically significantly better in the treatment group (2.3; SD = 1.4) than in the sham group (3.5; SD = 1.5; p<0.0001).
In the patients that crossed over to the treatment group, improvements in IPSS and Qmax at three months post-treatment were also reported to be statistically significant compared to baseline values (p<0.0001), as was IPSS-QOL (p=0.0024). All patients who received the active therapy were reported to have significantly improved IPSS, Qmax, and IPSS-QOL values compared to baseline at one and three years post-treatment.

Adverse events reported include one treated patient each who experienced nausea, vomiting, and de-novo urinary retention. In addition, among active treatment patients, 17% reported dysuria, 15% reported hematuria, 7% reported urinary frequency, and 7% reported hematospermia. This study is limited by duration of follow-up, with no control group present after three months of follow-up.

Nonrandomized Studies

Darson (2017) reported the results of a case series of 131 patients treated with transurethral convective radiofrequency water-vapor thermal therapy with LUTS associated with BPH.[7] Not all values were reported for all patients at all time-points. Statistical significance of changes from baseline was determined using a longitudinal general estimation-equation model using an exchangeable working correlation structure, which takes into account the correlation within a subject over time. IPSS at baseline, three to six months, and 12 months was 19.9 (SD = 6.7), 9.8 (SD = 6.9), and 10.1 (SD = 7.2). The three to six- and 12-month values were significantly lower than baseline (p<0.001). Qmax values at baseline, three to six, and 12 months were 8.7 (SD = 4.7), 11.6 (SD = 7.7), and 10 (SD = 5). The three- to six-month value was significantly different from baseline, but the 12-month value was not (p=0.04 and p=0.4, respectively). Improvement in IPSS-QOL scores from baseline to three-month follow-up was statistically significant, from 4.3 (SD = 1.2) to 2.3 (SD = 1.5; p<0.0001), and this statistically significant improvement was maintained at the 12-month follow-up. Urinary frequency, urgency, frequency and urgency, hematuria and nocturia were reported in less or equal to 4% of patients.

Dixon (2015 and 2016) reported the results of a case series in two publications.[8,9] A total of 65 men at or above the age of 45 experiencing LUTS secondary to BPH received convective radiofrequency thermal therapy. Results were gathered as self-administered questionnaires as well as measurements taken at scheduled follow-up visits over the following two years. Not all values were reported for all patients at all time-points. Statistical differences were calculated using a paired Student’s t-test for each measure. IPSS at one, three, 12, and 24 months was 14.8 (SD = 8.4), 8.3 (SD = 5.8), 9.2 (SD = 6.5), and 9.6 (SD = 6.5), respectively. All values were significantly improved compared to baseline (21.7 SD = 5.5; p<0.001). Qmax at one, three, 12, and 24 months was 9.9 (SD = 3.9), 12.8, 12.7 (SD = 6.3), and 12 (SD = 6.2). These values were also values were significantly improved compared to baseline (7.9 SD ± 3.2; p<0.001 except 24 months, where p=0.001). Improvement in IPSS-QOL scores from baseline to each time point reported were statistically significant (p<0.001). Adverse events reported were hematuria (14%), UTIs (20%), dysuria (22%), and urinary urgency (20%). All were mild to moderate transient events and 75% were reported within the first 30 days.

Section Summary

The evidence regarding transurethral water vapor thermal therapy of the prostate for the treatment of BPH includes one RCT and two case series. These studies report clinically significant improvements in several measures of urinary symptoms and quality of life.
However, there are limitations to the published evidence, which include limited comparative follow-up and lack of studies with no industry associations. Additional studies with longer comparative follow-up are needed to permit greater certainty regarding the effect of this treatment on health outcomes.

PRACTICE GUIDELINE SUMMARY

American Urological Association

The American Urological Association (AUA) published a 2018 evidence-based clinical practice guideline “Surgical Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: AUA Guideline,” which includes the following recommendation:[10]

Water vapor thermal therapy may be offered provided the prostate volume is <80g, however patients should be informed that evidence and safety (including longer-term retreatment rates) remains limited (conditional recommendation).

A conditional recommendation is described as:

- Balance between Benefits & Risks/Burdens unclear
- Alternative strategies may be equally reasonable
- Better evidence likely to change confidence

SUMMARY

It appears that transurethral water vapor thermal therapy of the prostate may improve urinary symptoms for some people with benign prostatic hyperplasia. More research is needed to know for sure. Therefore, transurethral water vapor thermal therapy of the prostate is considered investigational for all indications, including but not limited to benign prostatic hyperplasia.

REFERENCES

5. McVary, KT, Gange, SN, Gittelman, MC, et al. Minimally Invasive Prostate Convective Water Vapor Energy Ablation: A Multicenter, Randomized, Controlled Study for the


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**CODES**

*Date of Origin: December 2018*