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December 5, 2019

SUBJECT: Coverage for Transurethral Water Vapor Thermal Therapy for Benign Prostatic Hyperplasia.

Dear Medical Director,

The American Urological Association (AUA) with more than 15,000 members in the United States and represents the world's largest collection of expertise and insight into the treatment of urologic disease and provides invaluable support to the urologic community by fostering the highest standards of urologic care through education, research and the formulation of health policy.

The AUA considers *transurethral destruction of prostate tissue; by radio-frequency generated water thermotherapy*, also known as the Rezum® procedure, to be a viable treatment of men with benign prostatic hyperplasia (BPH) and therefore should be covered for reimbursement. The AUA does not consider this procedure to be investigational or experimental.

In September 2017, the American Medical Association (AMA) Current Procedural Terminology (CPT) Editorial Panel reviewed and accepted the creation of a Category I CPT code for *transurethral destruction of prostate tissue; by radio-frequency generated water thermotherapy*. AMA CPT codes are divided into three categories: Category I codes are assigned to well established services and procedures, Category II codes are used for performance measurement, data collection and tests results and Category III codes are temporary codes established to track emerging technology.

In order for a Category I code to be approved, the request must go through a rigorous approval process. Category I codes must meet the following AMA criteria to be granted a CPT code:

- All devices and drugs necessary for performance of the procedure or service have received FDA clearance or approval when such is required for performance of the procedure or service.
- The procedure or service is performed by many physicians or other qualified health care professionals across the United States.
- The procedure or service is performed with frequency consistent with the intended clinical use (i.e., a service for a

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common condition should have high volume, whereas a service commonly performed for a rare condition may have low volume).

- The procedure or service is consistent with current medical practice.
- The clinical efficacy of the procedure or service is documented in literature that meets the requirements set forth in the CPT code change application.

A Category I CPT code must also meet stringent literature requirements established by the AMA to prove clinical efficacy before a code is approved through the CPT Editorial Process. The Rezum® procedure met the entire Category I criteria.

In addition, the AUA has a stringent guideline development process and develops recommendations that are analysis-based or consensus-based, depending on guideline panel process and available data, for optimal clinical practices in the diagnosis and treatment of benign prostatic hyperplasia. The most current American Urological Association Guideline: Management of Benign Prostatic Hyperplasia (BPH) was published in 2018 and amended in 2019.

The AUA Guideline include the following statements:

Water Vapor Thermal Therapy

Water vapor thermal therapy may be offered to patients with LUTS attributed to BPH provided prostate volume <80g; however, patients should be counseled regarding efficacy and retreatment rates.

Water vapor thermal therapy may be offered to eligible patients who desire preservation of erectile and ejaculatory function.¹

Study results show that Rezum Water Vapor Therapy demonstrates significant sustained improvement of lower urinary tract symptoms (LUTS) and QOL for patients treated for benign prostatic hyperplasia (BPH) through 4 years post-procedure. Improvements as measured by IPSS, QOL, Qmax and BPHII show durability with consistent improvement from initial reporting at 3 months. In addition to symptom and QOL improvements, surgical retreatment was low, with surgical intervention performed on just 4.4% of subjects through 4 years. Study results show a positive safety profile with preservation of sexual function, and no late-occurring related adverse events or de novo erectile dysfunction reported at 4 years.²

The AUA would like to express the importance of providing patient choice for those patients who want to preserve ejaculation, who are not candidates for anesthesia as it can be done as an

¹ American Urological Association Guideline: Benign Prostatic Hyperplasia: Surgical Management of Benign Prostatic Hyperplasia/Lower Urinary Tract Symptoms. Available from [https://www.auanet.org/guidelines/benign-prostatic-hyperplasia-\(bph\)-guideline](https://www.auanet.org/guidelines/benign-prostatic-hyperplasia-(bph)-guideline) . 2018-reviewed-and-validity-confirmed-2019).

² J Urol. 2018 Aug; 200(2):405-413 (<https://www.auajournals.org/doi/pdf/10.1016/j.juro.2018.02.3088>). Retrieved December 5, 2019.



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in-office procedure, and in those with an enlarged obstructing median lobe who are not a candidate for prostatic urethral lift.

Therefore, the AUA believes that the Rezum® prostatic procedure should not be considered investigational but an appropriate therapeutic tool used by urologists. If a physician provides a service or procedure, has documented their work appropriately and indicates medical necessity, then according to insurer guidelines, these services should be covered. The clinical effectiveness has been proven by virtue of going through the CPT and is part of our guidelines. Patient choice is of utmost importance in caring for patients with urologic diseases, and limiting their choices does not allow a urologist to provide optimal patient care and is not providing optimal care for your insured population.

If you have any other questions about this request for coverage and reimbursement, please contact Stephanie N. Storck, Director of Payment Policy at 866-746-4282, extension 3786.

Sincerely,

A handwritten signature in black ink that reads "Jonathan Rubenstein".

Jonathan Rubenstein M.D.
Chair, Coding and Reimbursement Committee
American Urological Association