



American Urological Association

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U.S. Toll Free: 1-866-RING-AUA
(1-866-746-4282)

Phone: 410-689-3700

Fax: 410-689-3800

Email: AUA@AUAnet.org

Websites: AUAnet.org

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Dear Medical Director,

The American Urological Association (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 benign prostatic hyperplasia (BPH). Therefore, this procedure should be covered for reimbursement. The AUA does not consider this procedure to be investigational or experimental and, therefore, warrants coverage.

In September 2017, the American Medical Association (AMA) Current Procedural Terminology (CPT) Editorial Panel reviewed and accepted the creation of a new CPT code for *transurethral destruction of prostate tissue; by radio-frequency generated water thermotherapy*. Although this code will not be available for use until January 2019, the AUA believes insurance companies should cover the procedure until the release of the new CPT code.

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 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.

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In addition, the AUA has a stringent guideline development process and develop recommendations that are analysis-based or consensus-based, depending on Panel processes 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) (originally published in 2010) was reviewed and validity confirmed in 2014 and does not mention the Rezum® procedure as a treatment for BPH. The BPH guidelines are currently under review for release in 2018. Because literature on new technologies may not be available for review during the stringent AUA guidelines development process, the following disclaimer statement is included in the Guideline addressing this possibility.

Although guidelines are intended to encourage best practices and potentially encompass available technologies with sufficient data as of close of the literature review, they are necessarily time-limited. Guidelines cannot include evaluation of all data on emerging technologies or management, including those that are FDA-approved, which may immediately come to represent accepted clinical practices.

For this reason, the AUA does not regard technologies or management which are too new to be addressed by this guideline as necessarily experimental or investigational.

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 approval process.

In the case of an appeal by a physician, all correspondence should be directed to the medical office requesting the review of the denied claim and not the American Urological Association.

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

Sincerely,

Christopher Gonzalez, M.D.
Chair, AUA Public Policy Council

Jonathan Rubenstein, M.D.
Chair, AUA Coding and Reimbursement Committee

Ronald P. Kaufman, M.D.
AUA Advisor to AMA Current Procedural Terminology (CPT) Editorial Panel