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Dear Medical Director,

It has come to attention of the American Urological Association (AUA) that your insurance carrier considers the cystourethroscopic insertion of permanent adjustable transprostatic implants (also known as the Urolift® prostatic urethral lift procedure) as investigational and/or experimental in the treatment of benign prostatic hyperplasia (BPH). Therefore, this procedure is not covered for reimbursement. The AUA does not consider this procedure to be investigational or experimental and, therefore, warrants coverage.

In January 2015, the American Medical Association (AMA) Current Procedural Terminology (CPT) Editorial Panel established Category I CPT *code 52441 Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant* and *52442 Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; each additional permanent adjustable transprostatic implant (List separately in addition to code for primary procedure)*. These codes were created to enable reporting of this procedure to insurers.

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 Urolift® procedure met the entire Category I criteria.

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 Urolift® procedure as a treatment for BPH. 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.*
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> *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 Urolift® 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 not be denied on the basis of being experimental or investigational. 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,

David Penson, M.D., MPH
Chair, AUA Health Policy Council

Ronald P. Kaufman, M.D.
Chair, AUA Coding and Reimbursement Committee

Jeffrey A. Dann, M.D.
AUA Advisor to AMA Current Procedural Terminology (CPT) Editorial Panel