



MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 04/01/14
LAST REVIEW DATE:
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

PROSTATIC URETHRAL LIFT

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

Benign Prostatic Hypertrophy (BPH):

BPH is a non-cancerous enlargement of the prostate. As the prostate enlarges, it presses against the urethra causing the urethra to narrow. The bladder wall becomes thicker and begins to contract even when there is only a small amount of urine in the bladder. Eventually the bladder weakens and loses ability to empty completely.

Prostatic urethral lift (PUL) has been investigated as a minimally invasive procedure to relieve lower urinary tract symptoms (LUTS) associated with BPH. The UroLift® System has received FDA approval.

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PROSTATIC URETHRAL LIFT (cont.)

Criteria:

- Prostatic urethral lift for the treatment of urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) is considered **experimental or investigational** based upon:
 1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome, and
 3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
 4. Insufficient evidence to support improvement outside the investigational setting.

Resources:

1. Arenas da Silva LF, Schonthal M, Cruz F, et al. [New treatment strategies for male lower urinary tract symptoms]. *Urologe A*. Dec 2012;51(12):1697-1702.
2. Barkin J, Giddens J, Incze P, Casey R, Richardson S, Gange S. UroLift system for relief of prostate obstruction under local anesthesia. *Can J Urol*. Apr 2012;19(2):6217-6222.
3. Berges R, Sievert KD, Gratzke C, Wetterauer U. [UroLift(R): an operative non-ablative procedure for treatment of benign prostatic syndrome]. *Urologe A*. Mar 2013;52(3):350-353.
4. Chung A, Woo HH. What's truly minimally invasive in benign prostatic hyperplasia surgery? *Curr Opin Urol*. Jan 2014;24(1):36-41.
5. Delongchamps NB, Conquy S, Defontaines J, Zerbib M, Peyromaure M. [Intra-prostatic UroLift((R)) implants for benign prostatic hyperplasia: preliminary results of the four first cases performed in France]. *Prog Urol*. Sep 2012;22(10):590-597.
6. Garrido Abad P, Coloma Del Peso A, Sinues Ojas B, Fernandez Arjona M. [Urolift(R), a new minimally invasive treatment for patients with low urinary tract symptoms secondary to BPH. Preliminary results]. *Arch Esp Urol*. Jul-Aug 2013;66(6):584-591.



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PROSTATIC URETHRAL LIFT (cont.)

Resources: (cont.)

7. Larcher A, Broglia L, Lughezzani G, et al. Urethral lift for benign prostatic hyperplasia: a comprehensive review of the literature. *Curr Urol Rep.* Dec 2013;14(6):620-627.
8. McNicholas TA, Woo HH, Chin PT, et al. Minimally invasive prostatic urethral lift: surgical technique and multinational experience. *Eur Urol.* Aug 2013;64(2):292-299.

FDA 510K Summary for UroLift System:

- FDA-approved indication: The treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men 50 years of age or older.