HEALTH PLANS
UNIVERSITY OF UTAH

Medical Policy

Prostatic Urethral Lift (UroLift®) for Benign Prostatic Hypertrophy

Policy MP-073

Origination Date: 11/15/2021

Reviewed/Revised Date: 11/15/2021

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Disclaimer:

1. Policies are subject to change in accordance with State and Federal notice requirements.
2. Policies outline coverage determinations for U of U Health Plans Commercial, Healthy U (Medicaid) and Advantage U (Medicare) plans. Refer to the "Policy" section for more information.
3. This Medical Policy does not guarantee coverage or payment of the service. The service must be a benefit in the member's plan and the member must be eligible for coverage at the time of service. Additional payment guidelines may be applied that are not included in this policy.

Description:

Benign prostatic hyperplasia (BPH) is a common disorder among older men that results from hyperplastic nodules in the periurethral or transitional zone of the prostate. The normal prostate size for an adult male is 15cc to 30cc (one half ounce to one ounce). BPH prevalence increases with age and is present in more than 80% of men aged 70 to 79. The clinical manifestations of BPH include increased urinary frequency, urgency, nocturia, hesitancy, and weak stream. The urinary tract symptoms often progress with worsening hypertrophy and may lead to acute urinary retention, incontinence, renal insufficiency, and/or urinary tract infection.

Evaluation and management of BPH includes evaluation for other causes of lower urinary tract dysfunction (e.g., prostate cancer). Symptom severity determines the therapeutic approach. Therapies available include oral medications, surgical ablative procedures such as radiofrequency or microwave treatments, or transurethral resection of the prostate (TURP).

An alternative approach to ablation procedures or surgery is urethral lift procedure which stents the prostate tissues away for the urethra opening up the urethra to improved flow. The UroLift® System is a minimally invasive approach to treating BPH that holds the enlarged prostate tissue out of the way, so it no longer blocks the urethra. There is no cutting, heating, or removal of prostate tissue. This minimally invasive procedure is routinely done under local anesthesia in the office or outpatient setting. The delivery system is used by the physician to mechanically open the prostatic urethra by placing permanent implants across the lobes of the prostate to 2 separate the encroaching prostatic lobes. Every implant is assembled and tailored

in situ as it is delivered, based on the unique prostatic lobe characteristics. The transprostatic implants hold the prostatic urethra in a less obstructed configuration, thereby mitigating BPH symptoms. Each delivery device deploys one implant, and a typical procedure requires 4 implants (manufacturer reports since launch put the average number of implants used per procedure at 4.9), while most of the literature to date states mean slightly < 4 clips were used with a range of 2–7.

Policy Statement and Criteria

1. Commercial Plans

U of U Health Plans COVERS the urethral lift (Urolift®) procedures for the treatment of benign prostatic hyperplasia in limited circumstances.

Criteria for Coverage:

A. For men > 45 years of age;

B. Prostate gland volume is estimated to be ≤ 80 cc, by ultrasound or other radiological assessment;

C. Prostate anatomy demonstrates normal bladder neck without an obstructive or protruding median lobe;

D. Trial and Failure or intolerance of ≥ 3 months of conservative therapy unless otherwise contraindicated, which includes:

   i. Alpha-1-adrenergic antagonist; **AND**

   ii. A 5-alpha-reductase inhibitor.

E. Patient has had appropriate testing to exclude diagnosis of prostate cancer*;

F. Patient does not have a known allergy to nickel, titanium and/or stainless steel.

***** Prostate cancer testing: Prostate Specific Antigen (PSA) test results less than 3 nanograms per milliliter (ng/ml) is generally thought to represent low risk for prostate cancer. Levels at or above 3 ng/ml can have false positives and may not accurately reflect high risk, so additional testing may be needed (e.g., prostate biopsy, ultrasound, digital rectal exam)

U of U Health Plan considers use of prostatic urethral lift in all other situations is considered investigational when the above criteria are not met.

Repeat use of prostatic urethral lift as a treatment of BPH is considered investigational.

Use of prostatic urethral lift as a treatment of BPH after use of other minimally invasive procedures for BPH (e.g. transurethral water vapor therapy) is considered investigational.

Use of prostatic urethral lift as a treatment of BPH in a patient with a diagnosis of prostate cancer or in a patient who has been previously treated for prostate cancer is considered investigational.

Use of more than 7 implants in the treatment of BPH is considered investigational.

2. **Medicaid Plans**
   Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the U of U Health Plans Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website at: http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

   CPT/HCPCS codes covered by Utah State Medicaid may still require further evaluation to determine medical necessity for coverage.

3. **Medicare Plans**
   Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS and InterQual criteria are not available, the U of U Health Plans Commercial criteria will apply. For the most up-to-date Medicare policies and coverage, please visit their search website at: http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

Clinical Rationale

Currently, there is only one FDA cleared prostatic urethral device on the market. The NeoTract UroLift System UL400 (NeoTract, Pleasanton, CA) received clearance in December 2013 (after receiving clearance through FDA's de novo classification process in March 2013; K130651/DEN130023). In March 2016, the FDA determined that the UL500 was substantially equivalent to existing devices (UL400) for the treatment of symptoms of urinary flow obstruction secondary to benign prostatic hyperplasia in individuals aged 50 years and older. In 2017, the FDA expanded the indication for the UL400 and UL500 to include lateral and median lobe hyperplasia in men 45 years or older. An additional clearance in 2020 (K200441)2019 (K193269) modified one contraindication from men with prostate volume of >80 cc to men with prostate volume of >100 cc.

A 2015 multicenter RCT (Sonksen et al) published 12 months of results comparing the PUL procedure with TURP among individuals ages 50 and older with lower urinary tract symptoms, secondary to benign prostatic obstruction. The trial used a novel composite endpoint, referred to as the BPH6. Eligible patients had an International Prostate Symptom Score (IPSS) above 12, a Qmax of 15 mL/s or less for a 125-mL voided volume, a post-void residual volume less than 350 mL, and prostate volume of 60 cm3 or less on ultrasound. Patients were excluded if there was a median lobe obstruction in the prostate or signs of active infection. Criteria included reduction in IPSS by ≥30% within 12 months, relative to baseline; self-assessed by patients as ≥70% within 1 month, using a visual analog scale; reduction in

Sexual Health Inventory for Men (SHIM) score by ≤6 points within 12 months, relative to baseline; emission of semen as assessed by question 3 in the Male Sexual Health Questionnaire for Ejaculatory Dysfunction (MSHQ-EjD); incontinence Severity Index ≤4 points at all follow-up visits, and no treatment-related adverse events exceeding grade 1 on the Clavien-Dindo classification system at time of procedure or any follow-up. The study concluded that participants who underwent prostatic urethral lift responded significantly better than those who underwent transurethral resection of the prostate as therapy for benign prostatic hyperplasia with regard to important aspects of quality of life.

Also, in 2019, Rukstalis et al., noted results of the MedLift single-arm study. MedLift was an FDA IDE extension of the L.I.F.T. randomized study designed to examine safety and efficacy of PUL for treatment of obstructive middle lobes (OML). Inclusion criteria for this non-randomized cohort were identical to the L.I.F.T. randomized study, except for requiring an OML: >/= 50 years of age, IPSS >/= 13, and Qmax </= 12 ml/s. Results in the MedLift cohort were compared to the LIFT historical cohort. One patient required surgical retreatment and no implants were removed over the 12 months of follow-up.

Another 2019 systematic review (Jung et al) reported on PUL parallel-group RCTs published up to Jan 2019. The 2 included RCTs (N=297) were the LIFT and BPH6 trials which included different comparators and results were not combined meta-analytically. The authors used the GRADE approach to rate the certainty of the evidence. The review concluded PUL in comparison to TURP appears less effective in improving urological symptoms, both in the short-term and long-term (low-certainty evidence); PUL may result in a similar quality of life and erectile function; PUL may also result in better ejaculatory function; however, rates of major adverse event and retreatment are unclear.

Lastly, in 2020, Userovici, et al sought to show the efficacy of the UroLift® system after 7 years of experience. Urolift® implants were proposed between February 2012 and March 2019 for patients presenting symptomatic BPH, as an alternative for classic surgery. The effectiveness was evaluated with questionnaires about lower urinary tract symptoms (IPSS) and its impact on quality of life (IPSS-QdV). Tolerance was evaluated with questionnaires about erectile (IIEF5) and ejaculatory function (MSHQ-EjD) and complication rate. Survival without additional treatment was assessed using Kaplan-Meier method. Forty patients were treated during this period, with a median follow-up of 32 months. Three months after the procedure, IPSS and IPSS-QdV were significantly improved. MSHQ-EjD and IIEF5 were not modified. Two patients (5%) experienced a urinary retention and needed a bladder catheter. Survival without additional treatment at 5years was 63%. The authors concluded that Urolift® implants significantly improved the lower urinary tract symptoms in those with a good tolerance profile within the population. Moreover, greater than 60% of the patients did not need an additional treatment after 5 years of follow-up.

NICE reviewed the Urolift system in 2021 and supported adopting the UroLift System for treating lower urinary tract symptoms of benign prostatic hyperplasia, as it relieves lower urinary tract symptoms, avoids risk to sexual function, and improves quality of life. It can be done as a day-case or outpatient procedure for people aged 50 and older with a prostate volume between 30 and 80 ml. Its review noted current evidence available demonstrates that UroLift relieves lower urinary tract symptoms for up to 5 years. Also, since this is a minimally invasive procedure, it should be considered as an alternative to transurethral resection of the prostate (TURP) and holmium laser enucleation of the prostate (HoLEP).

Additional information in support of the NICE review is found in the published literature. In 2013, Roehrborn et al reported the first multicenter randomized blinded trial of the prostatic urethral lift for the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia (the L.I.F.T study). Since then Roehrborn et al has published 2 follow-up studies at 3 and 5 years post operation. There is data from 19 centers in North America and Australia for 206 patients (randomized 140 to

UroLift, 66 to control [sham]). Fifteen patients (10.7%) required revisions up to the 3-year follow-up and 13.6% required revisions at 5 years. Statistically significant improvements in International Prostate Symptom Scores (IPSS), peak flow-rate (Qmax), male sexual health questionnaire for ejaculatory dysfunction (MSHQ-EjD), and quality of life (QoL) scores were demonstrated; however, approximately one-third of the initial study patients experienced unsatisfactory results at 5 years.

The American Urological Association (AUA) evidence-based guideline, "Management of Benign Prostatic Hyperplasia/Lower Urinary Tract Symptoms" addresses surgical and minimally invasive procedures used in the treatment of benign prostatic hyperplasia (BPH)/Lower Urinary Tract Symptoms (LUTS). The AUA states that clinical scenarios exist where conservative management (e.g., medications, lifestyle changes) is either inadequate or inappropriate in which case consideration of one of the more invasive treatment modalities is warranted. Prostatic Urethral Lift (PUL) is discussed as one of the minimally-invasive treatments (MIST) in this guideline with the following statements:

- PUL should be considered as a treatment option for patients with LUTS/BPH provided prostate volume 30-80cc and verified absence of an obstructive middle lobe.
- PUL may be offered as a treatment option to eligible patients who desire preservation of erectile and ejaculatory function.

Applicable Coding

CPT Codes

52441 Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant

52442 Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; each additional permanent adjustable transprostatic implant (List separately in addition to code for primary procedure)

HCPCS Codes

C9739 Cystourethroscopy, with insertion of transprostatic implant; one to three implants

C9740 Cystourethroscopy, with insertion of transprostatic implant; four or more implants

References:

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