

<b>Policy</b>	<b>MM-070</b>
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Originated Department	Clinical Operations

## Standard operating Procedure (SOP) – Prostatic Urethral Lift (UroLift) for Benign Prostatic Hypertrophy

<b>Audience</b>
Providers, Members, Brokers, MHC

<b>Purpose</b>
<p>Medical policies provide general support for applying Mountain Health Co-Op member policy document coverage decisions and must reference the member-specific benefit plan document. The terms of the member-specific Policy document may differ from the standard benefit plan on which this medical policy is based. If there is a conflict between a member-specific policy document and the Mountain Health Co-Op medical policy, the member-specific policy document supersedes this medical policy. Any person(s) applying this medical policy must identify member eligibility, the member-specific policy document, and related policies or guidelines before applying this medical policy, including the existence of any state or federal guidance. Mountain Health Co-Op medical policies are designed for informational purposes only and are not an authorization, explanation of benefits, or contract. Receipt of benefits is subject to satisfaction of all terms and conditions of the member-specific policy document coverage. Mountain Health Co-Op reserves the sole discretionary right to modify all policies and guidelines at any time.</p>

<b>Definition</b>
<p>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.</p>

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 from 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 separate the encroaching prostatic lobes. Every implant is assembled and tailored. Additional payment guidelines may be applied that are not included in this policy. 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/Procedure

### Commercial Plans/CHIP

Mountain Health Co-op COVERS the urethral lift (Urolift®) procedures for the treatment of benign prostatic hyperplasia in limited circumstances.

#### 1. Criteria for Coverage:

- 1.1 For men > 45 years of age;
- 1.2 Prostate gland volume is estimated to be ≤ 80 cc, by ultrasound or other radiological assessment;
- 1.3 Prostate anatomy demonstrates normal bladder neck without an obstructive or protruding median lobe;
- 1.4 Trial and Failure or intolerance of ≥ 3 months of conservative therapy unless otherwise contraindicated, which includes:
  - a) Alpha-1-adrenergic antagonist; AND
  - b) A 5-alpha-reductase inhibitor.
- 1.5 Patient has had appropriate testing to exclude diagnosis of prostate cancer\*;
- 1.6 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).

**Mountain Health Co-op considers use of prostatic urethral lift in all other situations 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. Clinical Rationale**

**2.1** 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.

**2.2** 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 cm<sup>3</sup> 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  $\geq 30\%$  within 12 months, relative to baseline; self-assessed by patients as  $\geq 70\%$  within 1 month, using a visual analog scale; reduction in Sexual Health Inventory for Men (SHIM) score by  $\leq 6$  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  $\leq 4$  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.

- 2.3** 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:  $\geq 50$  years of age, IPSS  $\geq 13$ , and Qmax  $\leq$  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.
- 2.4** 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.
- 2.5** 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 5 years 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.
- 2.6** 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).
- 2.7** 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.

- 2.8** 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:
- a) 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.
  - b) 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

### **Vendors**

- **Personify**
- **HPS**

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### Review/Revision/Approval History

Date	Description
07/08/2024	New Policy
04/27/2026	Reviewed and approved by Mountain Health CO-OP Policy Committee

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