FEP 7.01.151 Prostatic Urethral Lift

Effective Date: April 15, 2018       Related Policies: None

Prostatic Urethral Lift

Description
Benign prostatic hyperplasia (BPH) is a common condition in older individuals that can lead to increased urinary frequency, an urgency to urinate, a hesitancy to urinate, nocturia, and a weak stream when urinating. The prostatic urethral lift (PUL) procedure involves the insertion of one or more permanent implants into the prostate, which retracts prostatic tissue and maintains an expanded urethral lumen.

FDA REGULATORY STATUS
One implantable transprostatic tissue retractor system has been cleared for marketing by FDA through the 510(k) process. In December 2013, the NeoTract UroLift® System UL400 (NeoTract, Pleasanton, CA) was cleared (after receiving clearance through FDA’s de novo classification process in March 2013; K130651/DEN130023). In March 2016, 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 age 50 years and older. FDA product code: PEW.

POLICY STATEMENT
Use of prostatic urethral lift in individuals with moderate-to-severe lower urinary tract obstruction due to benign prostatic hyperplasia may be considered medically necessary when all of the following criteria are met:

- Patient is not an appropriate candidate for a surgical procedure using general anesthesia, such as transurethral resection of the prostate, due to a chronic medical condition including but not limited to cardiopulmonary disease or chronic anticoagulation therapy.
- Patient has persistent or progressive lower urinary tract symptoms or is unable to tolerate medical therapy (α₁-adrenergic antagonists maximally titrated, 5α-reductase inhibitors, or combination medication therapy maximally titrated) over a trial period of no less than 6 months.
- Prostate gland volume is ≤80 mL.
- Prostate anatomy demonstrates normal bladder neck without an obstructive or protruding median lobe.
- Patient does not have urinary retention, urinary tract infection, or recent prostatitis (within past year).
- Patient does not have prostate-specific antigen level ≥3 ng/mL, or has had appropriate testing to exclude diagnosis of prostate cancer.
- Patient does not have a contact dermatitis nickel allergy.

Effective Date: April 15, 2018
Related Policies: None

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.
Use of prostatic urethral lift in other situations is considered **investigational.**

**BENEFIT APPLICATION**

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

**RATIONALE**

**Summary of Evidence**

For individuals who have lower urinary tract obstruction symptoms (due to BPH) and receive a PUL, the evidence includes systematic reviews, randomized controlled trials, and noncomparative studies. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, and treatment-related morbidity. One randomized controlled trial, the BPH6 study, compared the PUL procedure with transurethral resection of the prostate and reported that the PUL procedure was noninferior for the study’s composite end point, which required concurrent fulfillment of 6 independently validated measures of symptoms, safety, and sexual health. While transurethral resection of the prostate was superior to PUL in managing lower urinary tract symptoms, PUL did provide significant symptom improvement over 2 years. PUL was further superior to transurethral resection of the prostate in preserving sexual function. These findings were corroborated by another randomized controlled trial, entitled the LIFT study, which compared PUL with sham control. Patients underwent washout of BPH medications before enrollment. LIFT reported that patients with the PUL procedure, compared with patients who had sham surgery and no BPH medication, had greater improvements in lower urinary tract symptoms without worsened sexual function at 3 months. After 3 months, patients were given the option to have PUL surgery; 80% of the patients with sham procedures chose that option. Publications from this trial reported that functional improvements were durable over 3-, 4-, and 5-year follow-ups in a subset of patients treated with PUL; there was a high number of exclusions and loss to follow-up in that group. The evidence is sufficient to determine the effects of the technology on health outcomes.

**SUPPLEMENTAL INFORMATION**

**Practice Guidelines and Position Statements**

**European Association of Urology**

In 2017, the European Association of Urology updated its guidelines on urethral lift implants, giving a grade B recommendation for the use of UroLift in individuals with lower urinary tract symptoms who had prostates less than 70 mL with no middle lobe and were interested in preserving ejaculatory function. It noted that “long term effects have not been evaluated.”

**National Institute for Health and Care Excellence**

In 2014, the National Institute for Health and Care Excellence published interventional procedural guidance on urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia. The guidance stated:

“Current evidence on the efficacy and safety of insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia is adequate to support the use of this procedure.”

In 2015, the Institute published a medical technology guidance on the use of UroLift for treating lower urinary tract symptoms of benign prostatic hyperplasia. The guidance stated: “the UroLift system is effective in relieving symptoms of benign prostatic hyperplasia” and “the UroLift system should be considered as an alternative to current surgical procedures for use in a day-case setting in individuals
with lower urinary tract symptoms of benign prostatic hyperplasia who are aged 50 years and older and who have a prostate of less than 100 ml without an obstructing middle lobe.”

American Urological Association
The 2010 (reaffirmed 2014) American Urological Association guidelines on the management of benign prostatic hyperplasia did not address the prostatic urethral lift procedure.6

U.S. Preventive Services Task Force Recommendations

Medicare National Coverage
There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES
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POLICY HISTORY

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<th>Date</th>
<th>Action</th>
<th>Description</th>
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<tr>
<td>March 2018</td>
<td>Update Policy</td>
<td>Policy updated with literature review through October 9, 2017; references 4-5, 24, 28-29, and 31 added. Use of prostatic urethral lift in individuals with moderate to severe lower urinary tract obstruction due to benign prostatic hyperplasia may be considered medically necessary when all of the specified criteria are met.</td>
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