# Protocol

# Prostatic Urethral Lift

(701151)

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| **Medical Benefit** | | **Effective Date**: 02/01/20 | **Next Review Date**: 11/20 |
| **Preauthorization** | No | **Review Dates**: 05/17, 01/18, 01/19, 11/19 | |

***Preauthorization is not required.***

*The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

| Populations | Interventions | Comparators | Outcomes |
|---|---|---|---|
| Individuals:<br>• With lower urinary tract obstruction symptoms due to benign prostatic hyperplasia | Interventions of interest are:<br>• Prostatic urethral lift | Comparators of interest are:<br>• Transurethral resection of the prostate<br>• Minimally invasive prostate resection or ablation<br>• Continued medical management | Relevant outcomes include:<br>• Symptoms<br>• Functional outcomes<br>• Health status measures<br>• Quality of life<br>• Treatment-related morbidity |

## 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.

## SUMMARY OF EVIDENCE

For individuals who have lower urinary tract obstruction symptoms due to BPH who do not have sufficient response to medical therapy or are experiencing significant side effects with medical therapy and receive a PUL, the evidence includes systematic reviews, randomized controlled trials (RCTs), and noncomparative studies. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, and treatment-related morbidity. One RCT, 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 endpoint, which required concurrent fulfillment of six 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 two years. PUL was further superior to transurethral resection of the prostate in preserving ejaculatory function. These findings were corroborated by another RCT (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 three months. After three 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 three-, four-, and five-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 BPH6 and LIFT RCTs excluded men with median lobe obstruction. The published evidence supports a meaningful improvement in the net health outcome. Evidence reported through clinical input further supports that this use provides a clinically meaningful improvement in net health outcome and is consistent with generally accepted medical practice. Selection criteria of patients for whom evidence is sufficient to support improvement are derived from clinical trial eligibility criteria, product labeling, and clinical input. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

**POLICY**

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:

- The patient has persistent or progressive lower urinary tract symptoms despite medical therapy ($\alpha_1$-adrenergic antagonists maximally titrated, 5α-reductase inhibitors, or combination medication therapy maximally titrated) over a trial period of no less than a six months, or is unable to tolerate medical therapy; AND,
- Prostate gland volume is 80 mL or less; AND,
- Prostate anatomy demonstrates normal bladder neck without an obstructive or protruding median lobe; AND,
- Patient does not have urinary retention, urinary tract infection, or recent prostatitis (within past year); AND,
- Patient has had appropriate testing to exclude diagnosis of prostate cancer; AND,
- Patient does not have a known allergy to nickel, titanium or stainless steel.

Use of prostatic urethral lift in other situations is considered **investigational**.

**BACKGROUND**

BENIGN PROSTATIC HYPERPLASIA

BPH is a common disorder among older individuals that results from hyperplastic nodules in the periurethral or transitional zone of the prostate. BPH prevalence increases with age and is present in more than 80% of individuals ages 70 to 79.[1] The clinical manifestations of BPH include increased urinary frequency, nocturia, urgency or hesitancy to urinate, and a weak stream when urinating. The urinary tract symptoms often progress with worsening hypertrophy and may lead to acute urinary retention, incontinence, renal insufficiency, and/or urinary tract infection.

Two scores are widely used to evaluate BPH-related symptoms: the American Urological Association Symptom Index (AUASI) and the International Prostate Symptom Score (IPSS). The AUASI is a self-administered seven item questionnaire assessing the severity of various urinary symptoms.[2] Total AUASI scores range from zero to 35, with overall severity categorized as mild (≤7), moderate (8-19), or severe (20-35).[1] The IPSS incorporates questions from the AUASI and a quality of life question or a "Bother score."[3]

Management

Evaluation and management of BPH include assessment for other causes of lower urinary tract dysfunction (e.g., prostate cancer), symptom severity, and the degree that symptoms are bothersome to determine the therapeutic approach.

Medical Therapy

A discussion about medical therapy is generally indicated for patients with moderate-to-severe symptoms (e.g., an AUASI score of ≥8), bothersome symptoms, or both. Available medical therapies for BPH-related lower urinary tract dysfunction include α-adrenergic blockers (e.g., alfuzosin, doxazosin, tamsulosin, terazosin, silodosin), 5α-reductase inhibitors (e.g., finasteride, dutasteride), combination α-adrenergic blockers and 5α-reductase inhibitors, anti-muscarinic agents (e.g., darifenacin, solifenacin, oxybutynin), and phosphodiesterase-5 inhibitors (e.g., tadalafil).[1] In a meta-analysis of both indirect comparisons from placebo-controlled studies (including 6,333 patients) and direct comparative studies (including 507 patients), Djavan et al (1999) found that the IPSS improved by 30% to 40% and the Qmax score (mean peak urinary flow rate) improved by 16% to 25% in individuals assigned to α-adrenergic blockers.[4] Combination therapy using an α-adrenergic blocker and 5α-reductase inhibitor has been shown to be more effective for improving IPSS than either treatment alone, with median scores improving by more than 40% over one year and by more than 45% over four years.[5]

Surgical and Ablative Therapies

Patients who do not have sufficient response to medical therapy, or who are experiencing significant side effects with medical therapy, may be referred for surgical or ablative therapies. Various surgical and ablative procedures are used to treat BPH. Transurethral resection of the prostate is generally considered the reference standard for comparisons of BPH procedures.[6] In the perioperative period, transurethral resection of the prostate is associated with risks of any operative procedure (e.g., anesthesia risks, blood loss). Although short-term mortality risks are generally low, a large prospective study with 10,654 patients by Reich et al (2008) reported the following short-term complications: "failure to void (5.8%), surgical revision (5.6%), significant urinary tract infection (3.6%), bleeding requiring transfusions (2.9%), and transurethral resection syndrome (1.4%)."[7] Incidental carcinoma of the prostate was diagnosed by histologic examination in 9.8% of patients. In the longer term, transurethral resection of the prostate is associated with increased risk of sexual dysfunction and incontinence.

Several minimally invasive prostate ablation procedures are available, including transurethral microwave thermotherapy, transurethral needle ablation of the prostate, urethromicroablation phototherapy, and photoselective vaporization of the prostate. The minimally invasive procedures were individually compared with transurethral resection of the prostate at the time they were developed, which provided a general benchmark for evaluating those procedures.

**REGULATORY STATUS**

One implantable transprostatic tissue retractor system has been cleared for marketing by the Food and Drug Administration (FDA) through the 510(k) process. In 2013, the NeoTract UroLift® System UL400 (NeoTract) was cleared (after receiving clearance through the FDA's de novo classification process in March 2013; K130651/ DEN130023). In 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 BPH in individuals ages 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. FDA product code: PEW.

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Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced

procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

**REFERENCES**

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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