This protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.

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.

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

Description

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

Summary of Evidence

For individuals who have lower urinary tract obstruction symptoms due to BPH who receive 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. The LIFT study was an RCT comparing PUL with sham control that reported the PUL procedure is associated with greater improvements in lower urinary tract symptoms than medical management, without worsened sexual function. One publication from this trial reported that functional improvements were durable over three- and four-year follow-ups in a subset of patients, but this conclusion is limited because only treated patients were included in the longer follow-up and there was a high loss to follow-up in the treated group. Another RCT, the BPH6 study, compared the PUL procedure with transurethral resection of the prostate (TURP) and reported that PUL was noninferior for the study’s composite end point, which included multiple measures of symptoms and complications combined into a single score. While TURP was associated with greater improvements in urinary tract obstruction symptom outcomes, it was also associated with greater declines in sexual function than PUL. This small trial was limited by unequal dropout rates between groups after enrollment,
uncertainty about the validity of its primary composite outcome measure. The composite measure was composed mostly of safety items, and may have therefore favored the PUL group. Because of limitations with the BPH6 trial, its results do not definitively demonstrate the noninferiority of PUL to TURP; more evidence is needed to corroborate these results. In addition, follow-up in the available studies was inadequate to identify longer term adverse events. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy
The prostatic urethral lift procedure is considered investigational for all indications.

Medicare Advantage
Prostatic urethral lift procedures may be considered medically necessary when the all of the following criteria are met:

- The UroLift device is used for the treatment of symptomatic BPH in a member with well documented voiding symptoms consistent with prostatic hypertrophy; and
- AUA symptom index (AUASI) score greater than or equal to 13; and
- Peak urine flow rate (Qmax) less than or equal to 12 cc/sec on a voided volume that is greater than 125 cc; and
- The member has had an adequate trial of, but is refractory to or intolerant of, usual BPH medication; and
- The prostate volume is less than or equal to 80 cc without an obstructive median lobe; and
- There are no signs, symptoms, or diagnostic evidence of an active urinary infection and no history of bacterial prostatitis in the past three (3) months; and
- The member is a poor candidate for other surgical interventions for BPH due to underlying disease (e.g., cardiac disease, pulmonary disease, etc.) and/or at high risk of bleeding and/or the beneficiary has opted for PUL based on likelihood of preserving sexual function and/or there is another documented reason for opting for PUL.

Prostatic urethral lift procedures may be considered medically necessary for up to a total of six implants. Implants in excess of six may be reconsidered on an exception basis.

Background

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. BPH prevalence increases with age and is present in more than 80% of men ages 70 to 79.¹ 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.

Two scores are widely used to evaluate BPH-related symptoms. The American Urological Association Symptom Index (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 (seven or less),
moderate (eight to 19), or severe (20-35).1 The International Prostate Symptom Score incorporates questions from the AUASI and a quality of life question or “Bother score.”3

Management of BPH

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

Medical Therapy

A discussion about medical therapy is generally indicated for patients with moderate-to-severe symptoms (e.g., AUASI score, eight or more), 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

Surgical and Ablative Therapies

Various surgical or ablative procedures are used to treat BPH. TURP is generally considered the reference standard for comparisons of BPH treatments.4 In the perioperative period, TURP is associated with risks of any operative procedure (e.g., anesthesia risks, blood loss). Although short-term mortality risks are generally low, one large prospective study with 10,654 patients 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%).”5 Incidental carcinoma of the prostate was diagnosed by histologic examination in 9.8% of patients. In the longer term, TURP is associated with risk of sexual dysfunction and incontinence.

Several minimally invasive prostate ablation procedures have also been developed, including transurethral microwave thermotherapy, transurethral needle ablation of the prostate, urethromicroablation phototherapy, and photoselective vaporization of the prostate.

Prostatic Urethral Lift

The prostatic urethral lift procedure involves placement of one or more implants in the lateral lobes of the prostate using a transurethral delivery device. The implant device is designed to retract the prostate to allow expansion of the prostatic urethra. The implants are retained in the prostate to maintain an expanded urethral lumen.

One device, the NeoTract UroLift System, has been cleared for marketing by the U.S. Food and Drug Administration (see Regulatory Status section). The device has two main components: the delivery device and the implant. Each delivery device comes preloaded with one UroLift implant.

Outcome Measures to Evaluate BPH Symptoms

A number of health status measures are used to evaluate symptoms relevant to BPH and adverse effects of treatment for BPH, including urinary dysfunction, ejaculatory dysfunction, overall sexual health, and overall quality of life. Some validated scales are shown in Table 1.

Table 1. Health Status Measures Relevant to Benign Prostatic Hyperplasia

<table>
<thead>
<tr>
<th>Measure</th>
<th>Outcome Evaluated</th>
<th>Description</th>
<th>Clinically Meaningful Difference (If Known)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male Sexual Health Questionnaire for Ejaculatory Dysfunction (MSHQ-EjD)1</td>
<td>Ejaculatory function</td>
<td>Patient-administered, 4-item scale</td>
<td></td>
</tr>
<tr>
<td>Measure</td>
<td>Outcome Evaluated</td>
<td>Description</td>
<td>Clinically Meaningful Difference (If Known)</td>
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<tr>
<td>Sexual Health Inventory for Men (SHIM)⁷</td>
<td>Erectile function</td>
<td>Patient-administered, 5-item scale; final score range, 1 (worst symptoms) to 25 (fewest symptoms)</td>
<td></td>
</tr>
<tr>
<td>American Urological Association Symptom Index (AUASI)¹ ⁸</td>
<td>Severity of lower urinary tract symptoms</td>
<td>Patient-administered, 7-item scale; final score range, 0 (no symptoms) to 35 (worst symptoms)</td>
<td>Minimum of 3-point change¹ ⁸</td>
</tr>
<tr>
<td>International Prostate Symptom Score (IPSS)³</td>
<td>Severity of lower urinary tract symptoms</td>
<td>Patient-administered, 8-item scale</td>
<td></td>
</tr>
<tr>
<td>Benign Prostatic Hyperplasia Impact Index (BPH-II)⁴ ⁹</td>
<td>Effect of urinary symptoms on health domains</td>
<td>Patient-administered, 4-item scale; final score range, 0 (best) to 13 (worst)</td>
<td>Minimum of 0.4-point change⁷</td>
</tr>
</tbody>
</table>

### Regulatory Status

One implantable transprostatic tissue retractor system has been cleared for marketing by the U.S. Food and Drug Administration (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 men age 50 years and older. FDA product code: PEW.

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


