Medical Policy
Prostatic Urethral Lift

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Policy Number: 744
BCBSA Reference Number: 7.01.151
NCD/LCD: Local Coverage Determination (LCD): Prostatic Urethral Lift (PUL) (L36601)

Related Policies
None

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

The prostatic urethral lift procedure is considered INVESTIGATIONAL for all indications.

Medicare HMO BlueSM and Medicare PPO BlueSM Members

Medical necessity criteria and coding guidance for Medicare Advantage members living in Massachusetts can be found through the link below.

Local Coverage Determination (LCD): Prostatic Urethral Lift (PUL) (L36601)

For medical necessity criteria and coding guidance for Medicare Advantage members living outside of Massachusetts, please see the Centers for Medicare and Medicaid Services website for information regarding your specific jurisdiction at https://www.cms.gov.

Prior Authorization Information
Pre-service approval is required for all inpatient services for all products. See below for situations where prior authorization may be required or may not be required.

<table>
<thead>
<tr>
<th>Outpatient</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
<td>This is not a covered service.</td>
</tr>
<tr>
<td>Commercial PPO and Indemnity</td>
<td>This is not a covered service.</td>
</tr>
<tr>
<td>Medicare HMO BlueSM</td>
<td>No</td>
</tr>
<tr>
<td>Medicare PPO BlueSM</td>
<td>No</td>
</tr>
</tbody>
</table>
CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following CPT/HCPCS codes are considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

CPT Codes

<table>
<thead>
<tr>
<th>CPT codes:</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>52441</td>
<td>Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant</td>
</tr>
<tr>
<td>52442</td>
<td>Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; each additional permanent adjustable transprostatic implant (List separately in addition to code for primary procedure)</td>
</tr>
</tbody>
</table>

HCPCS Codes

<table>
<thead>
<tr>
<th>HCPCS codes:</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C9739</td>
<td>Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants</td>
</tr>
<tr>
<td>C9740</td>
<td>Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants</td>
</tr>
</tbody>
</table>

Description

Benign Prostatic Hyperplasia

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 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.

Two scores are widely used to evaluate BPH-related symptoms. The American Urological Association Symptom Index (AUASI) is a self-administered 7-item questionnaire assessing the severity of various urinary symptoms. Total AUASI scores range from 0 to 35, with overall severity categorized as mild (≤7), moderate (8-19), or severe (20-35). The International Prostate Symptom Score incorporates the questions from the AUASI and a quality of life question or “Bother score.”

Management of BPH

Evaluation and management of BPH includes evaluation for other causes of lower urinary tract dysfunction (eg, 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 (eg, AUASI score, ≥8), bothersome symptoms, or both. Available medical therapies for BPH-related lower urinary tract dysfunction include α-adrenergic blockers (eg, alfuzosin, doxazosin, tamsulosin, terazosin, silodosin), 5α-reductase inhibitors (eg, finasteride, dutasteride), combination α-adrenergic blockers and 5α-reductase inhibitors, anti-muscarinic agents (eg, darifenacin, solifenacin, oxybutynin), and phosphodiesterase-5 inhibitors (eg, tadalafil).
Surgical and Ablative Therapies
Various surgical or ablative procedures are used to treat BPH. Transurethral resection of the prostate (TURP) is generally considered the reference standard for comparisons of BPH treatments. In the perioperative period, TURP is associated with risks of any operative procedure (eg, anesthesia risks, blood loss). Although short-term mortality risks are generally low, 1 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%). 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 1 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 (NeoTract, Pleasanton, CA), has clearance for marketing by the U.S. Food and Drug Administration (FDA; see Regulatory Status section). The device has 2 main components: the delivery device and the implant. Each delivery device comes preloaded with 1 UroLift implant.

Outcome Measures Used in Evaluating 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 Measure 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)</td>
<td>Ejaculatory function</td>
<td>Patient-administered, 4-item scale</td>
<td></td>
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<tr>
<td>Sexual Health Inventory for Men (SHIM)</td>
<td>Erectile function</td>
<td>Patient-administered, 5-item scale; final score range, 1 (worst symptoms) to 25 (fewest symptoms)</td>
<td></td>
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<tr>
<td>American Urological Association Symptom Index (AUASI)</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>
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<tr>
<td>International Prostate Symptom Score (IPSS)</td>
<td>Severity of lower urinary tract symptoms</td>
<td>Patient-administered, 8-item scale</td>
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</table>
Summary
The evidence for prostatic urethral lift in patients with lower urinary tract obstruction symptoms due to BPH includes 2 randomized controlled trials (RCTs) and a number of noncomparative studies. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, and treatment-related morbidity. The LIFT trial reported that the prostatic urethral lift 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 a 3-year follow-up 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 compared the prostatic urethral lift procedure with transurethral resection of the prostate (TURP) and reported that the prostatic urethral lift 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 the prostatic urethral lift. This small trial was limited by unequal dropout rates between groups after enrollment, and uncertainty about the validity of its primary composite outcome measure. Because of limitations with the BPH6 trial, its results are not definitive in demonstrating noninferiority of the prostatic urethral lift to TURP, and further 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 History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>10/2016</td>
<td>New references added from BCBSA National medical policy.</td>
</tr>
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</table>

Information Pertaining to All Blue Cross Blue Shield Medical Policies
Click on any of the following terms to access the relevant information:
Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References


