Medical Policy
Prostatic Urethral Lift

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Policy Number: 744
BCBSA Reference Number: 7.01.151
NCD/LCD: NA

Related Policies
None

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

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.

Use of prostatic urethral lift in other situations is considered INVESTIGATIONAL.
Prior Authorization Information

Inpatient
- For services described in this policy, precertification/preauthorization **IS REQUIRED** if the procedure is performed inpatient.

Outpatient
- For services described in this policy, see below for situations where prior authorization might be required if the procedure is performed outpatient.

<table>
<thead>
<tr>
<th>Commercial Managed Care (HMO and POS)</th>
<th>Outpatient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial PPO and Indemnity</td>
<td>Prior authorization is <strong>not required</strong>.</td>
</tr>
<tr>
<td>Medicare HMO Blue℠</td>
<td>Prior authorization is <strong>not required</strong>.</td>
</tr>
<tr>
<td>Medicare PPO Blue℠</td>
<td>Prior authorization is <strong>not required</strong>.</td>
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</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 codes are included below for informational purposes only; this is not an all-inclusive list.*

The above medical necessity criteria **MUST** be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

**CPT Codes**

<table>
<thead>
<tr>
<th>CPT codes:</th>
<th>Code Description</th>
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<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>
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</table>

**HCPCS Codes**

<table>
<thead>
<tr>
<th>HCPCS codes:</th>
<th>Code Description</th>
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</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>
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</table>

The following ICD Diagnosis Code is considered medically necessary when submitted with the CPT and/or HCPCS codes above if medical necessity criteria are met:

**ICD-10 Diagnosis Coding**

<table>
<thead>
<tr>
<th>ICD-10-CM-diagnosis codes:</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>N40.1</td>
<td>Benign prostatic hyperplasia with lower urinary tract symptoms</td>
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</table>
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. The clinical manifestations of BPH include increased urinary frequency, nocturia, an 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. Total AUASI scores range from 0 to 35, with overall severity categorized as mild (≤7), moderate (8-19), or severe (20-35). The IPSS incorporates questions from the AUASI a quality of life question or a “Bother score.”

Medical Therapy
A discussion about medical therapy is generally indicated for patients with moderate-to-severe symptoms (eg, an AUASI score of ≥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). A 1999 meta-analysis of both indirect comparisons from placebo-controlled studies (including 6333 patients) and direct comparative studies (including 507 patients) 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. 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 1 year and by more than 45% over 4 years.

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 or ablative procedures are used to treat BPH. Transurethral resection of the prostate is generally considered the reference standard for comparisons of BPH procedures. In the perioperative period, transurethral resection of the prostate 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, transurethral resection of the prostate is associated with increased 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, transurethral microwave ablation 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.

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 (FDA; see Regulatory Status section). The device has 2 main components: the delivery device and the implant. Each delivery device comes preloaded with a UroLift implant.

Outcome Measures to Evaluate BPH Symptoms
A number of health status measures are used to evaluate symptoms relevant to BPH and adverse events of treatment for BPH, including urinary dysfunction, ejaculatory dysfunction, overall sexual health, and overall quality of life. Of note, prostate volume does not have a direct correlation with severity of urinary symptoms. Some validated scales are shown in Table 1.

Table 1. Health Outcome 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)⁹</td>
<td>Ejaculatory function and quality of life</td>
<td>Patient-administered, 4-item scale. Symptoms rated as absent (15) to severe (0). QOL issues assessed as no problem (0) to extremely bothered (5).</td>
<td></td>
</tr>
<tr>
<td>Sexual Health Inventory for Men (SHIM)¹⁰</td>
<td>Erectile function</td>
<td>Patient-administered, 5-item scale. Erectile dysfunction rated as severe (1-7), moderate (8-11), mild to moderate (12-16), or mild (17-21). Fewest symptoms present for patients with scores 22-25.</td>
<td></td>
</tr>
<tr>
<td>American Urological Association Symptom Index (AUASI); International Prostate Symptom Score (IPSS)¹,³,¹¹</td>
<td>Severity of lower urinary tract symptoms</td>
<td>Patient-administered, 7-item scale. Symptoms rated as mild (0-7), moderate (8-19), or severe (20-35). IPSS asks an additional question, rating QOL as delighted (0) to terrible (6).</td>
<td>Minimum of 3-point change¹,¹¹ Minimum of 30% change¹²</td>
</tr>
<tr>
<td>Benign Prostatic Hyperplasia Impact Index (BPH-II)⁶,¹³</td>
<td>Effect of urinary symptoms on health domains</td>
<td>Patient-administered, 4-item scale. Symptoms rated as absent (0) to severe (13).</td>
<td>Minimum of 0.4-point change¹¹</td>
</tr>
</tbody>
</table>

QOL: quality of life.

Summary
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.
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 fulfilment 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.

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


