Prostatic Urethral Lift

Description of Procedure or Service

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 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 (AUA-SI) is a self-administered 7-item questionnaire assessing the severity of various urinary symptoms. Total AUA-SI 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 AUA-SI 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 (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., AUA-SI score, ≥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).

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 (e.g., 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.
Prostatic Urethral Lift

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 (PUL)**

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.

**Regulatory Status**

One implantable transprostatic tissue retractor system has been cleared for marketing by FDA through the 510(k) process. The NeoTract UroLift System UL400 (NeoTract, Pleasanton, CA) received clearance in December 2013 (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.

***Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.

**Policy**

The prostatic urethral lift procedure is considered investigational. BCBSNC does not provide coverage for investigational services or procedures.

**Benefits Application**

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

**When Prostatic Urethral Lift is covered**

Not applicable.

**When Prostatic Urethral Lift is not covered**

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

**Policy Guidelines**

The evidence for prostatic urethral lift in patients with lower urinary tract obstruction symptoms due to BPH 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 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 3- and 4-year follow-ups in a subset of patients, but this conclusion is limited because only...
Prostatic Urethral Lift

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 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. 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 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.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 52441, 52442, C9739, C9740

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources


Policy Implementation/Update Information

10/30/15   New policy issued. Prostatic urethral lift is considered investigational. (sk)


Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.