Medical Coverage Policy | Prostatic Urethral Lifts

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OVERVIEW

Benign prostatic hyperplasia 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 1 or more permanent implants into the prostate, which retract prostatic tissue and maintain an expanded urethral lumen.

MEDICAL CRITERIA

Blue CHiP for Medicare and Commercial Products

The prostatic urethral lift procedure is considered medically necessary when the ALL of the following criteria are met:

- The UroLift device is used for the treatment of symptomatic BPH when there is 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
- There 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 beneficiary 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.

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Blue CHiP for Medicare and Commercial Products

The prostatic urethral lift procedure is considered medically necessary when all of the criteria are met.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable not medically necessary benefits/coverage.

BACKGROUND

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.

Management

Evaluation and management of BPH include assessment 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, 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).1 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.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 1 year and by more than 45% over 4 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 or 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 (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%)."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 have also been developed, 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.

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.

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 outcome

CODING

Blue CHiP for Medicare and Commercial Products
The following codes are medically necessary when the medical criteria is met:
52441 Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant
52442 each additional permanent adjustable transprostatic implant (List separately in addition to code for primary procedure)
C9739 Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants (**For institutional providers use only)**
C9740 Cystourethroscopy, with insertion of transprostatic implant; 4 or more
Implants (**For institutional providers use only)**

RELATED POLICIES

None

PUBLISHED

Provider Update, November/December 2018
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