Medical Coverage Policy | Prostatic Urethral Lifts

EFFECTIVE DATE:01|01|2023
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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

Medicare Advantage Plans and Commercial Products

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:

- The individual has persistent or progressive lower urinary tract symptoms despite 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, or is unable to tolerate medical therapy; AND,
- Prostate gland volume is ≤80 mL; AND,
- Prostate anatomy demonstrates normal bladder neck without an obstructive or protruding median lobe; AND,
- Individual does not have urinary retention, urinary tract infection, or recent prostatitis (within past year);AND,
- Individual has had appropriate testing to exclude diagnosis of prostate cancer; AND,
- Individual does not have a known allergy to nickel, titanium or stainless steel.

PRIOR AUTHORIZATION

Prior authorization is required for Medicare Advantage Plans and recommended for Commercial Products via the online tool for participating providers. See the Related Policies section.

POLICY STATEMENT

Medicare Advantage Plans and Commercial Products

Use of prostatic urethral lift is considered medically necessary when all the criteria above has been met.

Use of prostatic urethral lift in other situations, including repeat procedures, is considered not covered for Medicare Advantage Plans and not medically necessary for Commercial Products as the evidence is insufficient to determine that the technology results in an improvement in the net health outcomes.

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 (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 (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

Medicare Advantage Plans and Commercial Products

The following code(s) are medically necessary when the medical criteria are 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

Prior Authorization via Web-Based Tool for Procedures

PUBLISHED

Provider Update, November 2022
Provider Update, September 2021
Provider Update, September 2020
Provider Update, September 2019
Provider Update, November/December 2018

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