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Preauthorization is not required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

RELATED PROTOCOL

None

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> • With lower urinary tract obstruction symptoms due to benign prostatic hyperplasia who do not have sufficient response to medical therapy or are experiencing significant side effects with medical therapy 	Interventions of interest are: <ul style="list-style-type: none"> • Prostatic urethral lift 	Comparators of interest are: <ul style="list-style-type: none"> • Transurethral resection of the prostate • Minimally invasive prostate resection or ablation • Continued medical management 	Relevant outcomes include: <ul style="list-style-type: none"> • Symptoms • Functional outcomes • Health status measures • Quality of life • Treatment-related morbidity

DESCRIPTION

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.

SUMMARY OF EVIDENCE

For individuals who have lower urinary tract obstruction symptoms due to BPH who do not have a sufficient response to medical therapy or are experiencing significant side effects with medical therapy and receive a PUL, the evidence 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. One RCT, 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 endpoint, which required concurrent fulfillment 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. Prostatic urethral lift was further superior to transurethral resection of the prostate in preserving ejaculatory function. These findings were corroborated by another RCT (the Luminal Improvement Following Prostatic Tissue Approximation for the Treatment of Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia [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 these findings were preserved in a subset of patients over 3 to 5 years; however, a high number of patients were either excluded or lost to follow-up during this time. The BPH6 and LIFT RCTs included men with a prostate volume up to 80 cm³ and excluded men with median lobe obstruction. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have lower urinary tract obstruction symptoms due to BPH who have had a prior PUL procedure who are treated with a repeat PUL, the evidence includes long-term follow-up data from the LIFT study, a systematic review, and reports on clinical care setting real world experience. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, and treatment-related morbidity. Clinical data on the occurrence of repeat PUL, and consensus on clinically relevant definitions of retreatment/reintervention and subsequent outcomes are lacking. The 5 year surgical reintervention rate in the LIFT study was reported as 13.6%, while a meta-analysis concluded that the surgical reintervention rate following PUL is 6% per year. An analysis of clinical care setting real world experience reported the overall retreatment rate at 1 and 2 years to be 5.2% (95% confidence interval [CI], 4.2 to 6.1) and 11.9% (95% CI, 10.1 to 13.6), respectively, following an initial PUL. A retrospective healthcare system database analysis of endoscopic procedures for BPH found that patients treated with PUL were almost twice as likely to be retreated at 2-year follow-up compared to those receiving transurethral resection of the prostate (odds ratio, 1.78; p<.01). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

POLICY

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 patient has persistent or progressive lower urinary tract symptoms despite medical therapy (α_1 -adren-
ergic antagonists maximally titrated, 5 α -reductase inhibitors, or combination medication therapy maximally
titrated) over a trial period of no less than a six months, or is unable to tolerate medical therapy; AND,
- Prostate gland volume is 80 mL or less; AND,
- Prostate anatomy demonstrates normal bladder neck without an obstructive or protruding median lobe;
AND,
- Patient does not have urinary retention, urinary tract infection, or recent prostatitis (within past year); AND,
- Patient has had appropriate testing to exclude diagnosis of prostate cancer; AND,
- Patient does not have a known allergy to nickel, titanium or stainless steel.

Use of prostatic urethral lift in other situations, including repeat procedures, is considered **investigational**.

BACKGROUND

BENIGN PROSTATIC HYPERPLASIA

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. The clinical manifestations of BPH include increased urinary frequency, nocturia, 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. Benign prostatic hyperplasia prevalence increases with age and is present in more than 80% of individuals ages 70 to 79 years.¹

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 7-item questionnaire assessing the severity of various urinary symptoms.² Total AUASI scores range from 0 to 35, with overall severity categorized as mild (≤ 7), moderate (8-19), or severe (20-35).¹ The IPSS incorporates questions from the AUASI and a quality of life question or a "Bother score."³

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 to determine the therapeutic approach.

For patients with moderate-to-severe symptoms (e.g., an AUASI score of ≥ 8), bothersome symptoms, or both, a discussion about medical therapy is reasonable. Benign prostatic hyperplasia should generally be treated medically first. Available medical therapies for BPH-related lower urinary tract dysfunction include α -adrenergic blockers (e.g., alfuzosin, doxazosin, tamsulosin, terazosin, silodosin), 5 α -reductase inhibitors (e.g., finasteride, dutasteride), combination α -adrenergic blockers and 5 α -reductase inhibitors, anti-muscarinic agents (e.g., darifenacin, solifenacin, oxybutynin), and phosphodiesterase-5 inhibitors (e.g., tadalafil).¹ In a meta-analysis of both indirect comparisons from placebo-controlled studies (including 6,333 patients) and direct comparative studies (including 507 patients), Djavan et al (1999) 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 5 α -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.

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 and ablative procedures are used to treat BPH. Transurethral resection of the prostate (TURP) is generally considered the reference standard for comparisons of BPH procedures.⁵ 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, a large prospective study with 10,654 patients by Reich et al (2008) 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%)."⁶ Incidental carcinoma of the prostate was diagnosed by histologic examination in 9.8% of patients. In the longer term, TURP is associated with an increased risk of sexual dysfunction and incontinence.

Several minimally invasive prostate ablation procedures are available, 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 TURP at the time they were developed, which provided a general benchmark for evaluating those procedures. The American Urological Association (AUA) recommends surgical intervention for patients who have "renal insufficiency secondary to BPH, refractory urinary retention secondary to BPH, recurrent urinary tract infections

(UTIs), recurrent bladder stones or gross hematuria due to BPH, and/or with lower urinary tract symptoms (LUTS) attributed to BPH refractory to and/or unwilling to use other therapies.”⁷

REGULATORY STATUS

One implantable transprostatic tissue retractor system has been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. In 2013, the NeoTract UroLift® System UL400 (NeoTract) was cleared (after receiving clearance through the FDA’s de novo classification process in March 2013; K130651/DEN130023). In 2016, the FDA determined that the UL500 was substantially equivalent to existing devices (UL400) for the treatment of symptoms of urinary flow obstruction secondary to BPH in individuals ages 50 years and older. In 2017, the FDA expanded the indication for the UL400 and UL500 to include *lateral and median* lobe hyperplasia in men 45 years or older. An additional clearance in 2019 (K193269) modified an existing contraindication for use from men with a prostate volume of >80 cc to men with a prostate volume of >100 cc. FDA product code: PEW.

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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