

## MEDICAL POLICY – 7.01.598

### Prosthetic Urethral Lift

BCBSA Ref. Policy: 7.01.151

Effective Date: **Oct. 3, 2025**

Last Revised: Jun. 10, 2025

Replaces: N/A


RELATED MEDICAL POLICIES:

7.01.175 Temporarily Implanted Nitinol Device (iTind) for Benign Prostatic Hyperplasia

Select a hyperlink below to be directed to that section.

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## Introduction

Benign prostatic hyperplasia (BPH) is a common condition that affects many individuals as they get older. It happens when the prostate gland gets larger and presses on the urethra, causing problems like frequent or weak urine stream, or trouble starting urination. Treatment depends on how bothersome the symptoms are and can range from simply monitoring the condition to using medications or having surgery. Medications often include drugs that relax the prostate or shrink it over time. If symptoms become more severe, surgery may be recommended. The prostatic urethral lift (PUL) procedure uses tiny implants to move the enlarged prostate tissue out of the way. The procedure can be performed under minimal anesthesia and is purported to cause fewer side effects than traditional surgery, helps urine flow more easily, and helps to preserve sexual function. This policy describes when PUL may be considered medically necessary.

**Note:** The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

## Policy Coverage Criteria

Surgery	Medical Necessity
<b>Prostatic Urethral Lift</b>	<p><b>The Prostatic Urethral Lift procedure in individuals with moderate-to-severe lower urinary tract obstruction due to benign prostatic hyperplasia may be considered medically necessary when ALL of the below criteria are met:</b></p> <ul style="list-style-type: none"> <li>• The individual has persistent or progressive lower urinary tract symptoms despite medical therapy (see below section on medical therapy: <math>\alpha_1</math>-adrenergic antagonists, 5<math>\alpha</math>-reductase inhibitors, or combination medication therapy) over a trial period of no less than 6 months, or is unable to tolerate medical therapy; AND</li> <li>• Prostate gland volume is less than or equal to 80 mL; AND</li> <li>• Prostate anatomy demonstrates normal bladder neck without an obstructive or protruding median lobe; AND</li> <li>• Individual does not have urinary retention related to conditions other than benign prostatic hyperplasia, urinary tract infection, or recent prostatitis (within past year); AND</li> <li>• Individual does not have a diagnosis of prostate cancer</li> </ul> <p><b>Use of the prostatic urethral lift procedure in all other situations including repeat procedures is considered investigational.</b></p>

## Documentation Requirements

**The patient's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:**

- Office visit notes that contain the relevant history and physical  
No other significant causes of urinary retention besides enlarged prostate, UTI or prostatitis  
No diagnosis of prostate cancer

**AND**

- Chart documentation on prostate gland size and anatomy (chart notes or imaging results)

## Coding

Code	Description
<b>CPT</b>	
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)
<b>HCPCS</b>	
C9739	Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants
C9740	Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

## Evidence Review

### 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.<sup>1</sup>

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.<sup>2</sup> Total AUASI scores range from 0 to 35, with overall severity categorized as mild



( $\leq 7$ ), moderate (8-19), or severe (20-35).<sup>1</sup> The IPSS incorporates questions from the AUASI and a quality of life question or a "Bother score."<sup>3</sup>

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  $\geq 8$ ), 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  $\alpha$ -adrenergic blockers (e.g., alfuzosin, doxazosin, tamsulosin, terazosin, silodosin),  $5\alpha$ -reductase inhibitors (e.g., finasteride, dutasteride), combination  $\alpha$ -adrenergic blockers and  $5\alpha$ -reductase inhibitors, anti-muscarinic agents (e.g., darifenacin, solifenacin, oxybutynin), and phosphodiesterase-5 inhibitors (e.g., tadalafil).<sup>1</sup> 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  $\alpha$ -adrenergic blockers.<sup>4</sup> Combination therapy using an  $\alpha$ -adrenergic blocker and  $5\alpha$ -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.<sup>5</sup> 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%)."<sup>6</sup> 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."<sup>7</sup>

## Summary of Evidence

For individuals who have lower urinary tract obstruction symptoms due to benign prostatic hyperplasia (BPH) who do not have sufficient response to medical therapy or are experiencing significant side effects with medical therapy and receive a prostatic urethral lift (PUL), the evidence includes systematic reviews, randomized controlled trials (RCTs), and nonrandomized 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 (TURP) 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 TURP was superior to PUL in managing lower urinary tract symptoms, PUL did provide significant symptom improvement over 2 years. PUL was further superior to TURP in preserving ejaculatory function. These findings were corroborated by another RCT (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 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 cm<sup>3</sup> 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, systematic reviews, and reports on 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 TURP (odds ratio [OR], 1.78;  $p < .01$ ). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

## **Additional Information**

### **2017 Input**

Clinical input was sought to help determine whether the use of PUL for individuals with lower urinary tract obstruction symptoms due to BPH who do not have sufficient response to medical therapy or are experiencing significant side effects with medical therapy would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, while this policy was under review in 2017, clinical input on the use of a PUL for 3 indications were received from 4 respondents, including 2 physician-level responses identified through a specialty society and 2 physician-level responses identified through an academic medical center. Input consistently supported that the use of PUL for individuals with moderate-to-severe lower urinary tract obstruction symptoms due to BPH provides a clinically meaningful improvement in net health outcome and indicates this use is consistent with generally accepted medical practice.

### **Ongoing and Unpublished Clinical Trials**

Some currently ongoing and unpublished trials that might influence this review are listed in [Table 1](#).

**Table 1. Summary of Key Trials**

NCT No.	Trial Name	Planned Enrollment	Completion Date
<b>Ongoing</b>			
<b>NCT06037356</b>	Prostatic Urethral Lift Versus Transurethral Resection of Prostate in Benign Prostatic Hyperplasia Patients With Urinary Retention	100	May 2032 (recruiting)
<b>NCT04987892<sup>a</sup></b>	Investigating Medication vs. Prostatic Urethral Lift: Assessment and Comparison of Therapies for Benign Prostatic Hyperplasia	250	Oct 2025 (recruiting)
<b>NCT05784558<sup>a</sup></b>	RELIEF Study: Real-world Evaluation of LUTS Interventions and Patient Experience During Follow-up	2500	Dec 2030 (not yet recruiting)

NCT: national clinical trial.

<sup>a</sup> Denotes industry-sponsored or cosponsored trial.

## Clinical Input from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

### 2017

Clinical input was sought to help determine whether the use of PUL for individuals with lower urinary tract obstruction symptoms due to BPH who do not have sufficient response to medical therapy or are experiencing significant side effects with medical therapy would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, while this policy was under review in 2017, clinical input on the use of a prostatic urethral lift for 3 indications were received from 4 respondents, including 2 physician-level responses identified through a specialty society and 2 physician-level responses identified through an academic medical center. Input consistently supported that the use of PUL for individuals with moderate-to-severe lower urinary tract

obstruction symptoms due to BPH provides a clinically meaningful improvement in net health outcome and indicates this use is consistent with generally accepted medical practice.

## Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

## American Urological Association

In 2018, the American Urological Association published guidelines on the surgical management of LUTS attributed to BPH; the 2018 guidelines were most recently amended in 2021.<sup>7</sup> The guidelines made the following recommendations and statements regarding prostatic urethral lift (PUL).

- "PUL may be offered as an option for patients with LUTS [lower urinary tract symptoms] /BPH [benign prostatic hyperplasia] provided prostate volume 30-80cc and verified absence of an obstructive middle lobe "
  - "Moderate Recommendation; Evidence Level: Grade C indicating "Benefits > Risks/Burdens (or vice versa); Net benefit (or net harm) appears moderate. Applies to most patients in most circumstances but better evidence is likely to change confidence"
- "PUL may be offered as a treatment option to eligible patients who desire preservation of erectile and ejaculatory function."
  - "Conditional Recommendation; Evidence Level: Grade C indicating "Risks/Burdens unclear; Alternative strategies may be equally reasonable. Better evidence likely to change confidence"



- "Clinicians should inform patients of the possibility of treatment failure and the need for additional or secondary treatments when considering surgical and minimally-invasive treatments for LUTS/BPH."
- "Surgery is recommended 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 LUTS/BPH refractory to or unwilling to use other therapies."

## National Institute for Health and Care Excellence (NICE)

In 2014, the National Institute for Health and Care Excellence published guidance on urethral lift implants to treat lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH).<sup>49</sup> The guidance stated:

"Current evidence on the efficacy and safety of insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia is adequate to support the use of this procedure."

In 2021, the National Institute for Health and Care Excellence published updated guidance on the use of UroLift for treating LUTS of BPH.<sup>50</sup> The guidance stated: "the UroLift system relieves lower urinary tract symptoms, avoids risk to sexual function, and improves quality of life " and "the UroLift system should be considered as an alternative to transurethral resection of the prostate (TURP) and holmium laser enucleation of the prostate (HoLEP). It can be done as a day-case or outpatient procedure for people aged 50 and older with a prostate volume between 30 and 80 mL."

## Medicare National Coverage

There is no national coverage determination for the prostatic urethral lift procedure.

## Regulatory Status

One implantable transprostatic tissue retractor system has been cleared for marketing by the US 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.

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## History

Date	Comments
10/13/15	New Policy. Policy created with literature review through July 6, 2015. Prostatic urethral lift procedure with an implantable transprostatic tissue retractor/implant system as a treatment for BPH is considered investigational.
10/11/16	Annual Review. Policy updated with literature review through July 10, 2016; references 11, 21-22, 24, 26, and 28 added. Policy statement unchanged.
07/31/17	Archive policy due to 5 year results show positive outcomes and minimal side effects and overall less risky than TURP.
07/01/25	New policy, approved June 10, 2025, effective for dates of service on or after October 3, 2025, following 90-day provider notification. Policy updated with literature review through June 14, 2024; reference added.

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2025 Premera All Rights Reserved.

**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to



the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

