



## MASSACHUSETTS

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# Medical Policy

## Prostatic Urethral Lift

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### Policy Number: 744

BCBSA Reference Number: 7.01.151

NCD/LCD: NA

### Related Policies

None

### Policy

#### **Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue<sup>SM</sup> and Medicare PPO Blue<sup>SM</sup> Members**

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 ( $\alpha$ 1-adrenergic antagonists maximally titrated, 5 $\alpha$ -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  $\leq$ 80 mL; **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 is considered **INVESTIGATIONAL**.

## Prior Authorization Information

### Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** if the procedure is performed **inpatient**.

### Outpatient

- For services described in this policy, see below for situations where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is <b>not required</b> .
Commercial PPO and Indemnity	Prior authorization is <b>not required</b> .
Medicare HMO Blue <sup>SM</sup>	Prior authorization is <b>not required</b> .
Medicare PPO Blue <sup>SM</sup>	Prior authorization is <b>not required</b> .

## CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

*The following codes are included below for informational purposes only; this is not an all-inclusive list.*

The above **medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:**

### CPT Codes

CPT codes:	Code Description
52441	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant
52442	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; each additional permanent adjustable transprostatic implant (List separately in addition to code for primary procedure)

### HCPCS Codes

HCPCS codes:	Code Description
C9739	Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants
C9740	Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants

The following ICD Diagnosis Code is considered medically necessary when submitted with the CPT and/or HCPCS codes above if **medical necessity criteria** are met:

### ICD-10 Diagnosis Coding

ICD-10-CM-diagnosis codes:	Code Description
N40.1	Benign prostatic hyperplasia with lower urinary tract symptoms

## Description

### 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 ages 70 to 79.<sup>1</sup> 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.

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>

### **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 to 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  $\geq 8$ ), bothersome symptoms, or both. Available medical therapies for BPH-related lower urinary tract dysfunction include  $\alpha$ -adrenergic blockers (eg, alfuzosin, doxazosin, tamsulosin, terazosin, silodosin), 5 $\alpha$ -reductase inhibitors (eg, finasteride, dutasteride), combination  $\alpha$ -adrenergic blockers and 5 $\alpha$ -reductase inhibitors, anti-muscarinic agents (eg, darifenacin, solifenacin, oxybutynin), and phosphodiesterase-5 inhibitors (eg, tadalafil).<sup>1</sup> In a meta-analysis of both indirect comparisons from placebo-controlled studies (including 6333 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.<sup>5</sup>

### **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 and ablative procedures are used to treat BPH. Transurethral resection of the prostate is generally considered the reference standard for comparisons of BPH procedures.<sup>6</sup> 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, a large prospective study with 10654 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>7</sup> 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 are available, including transurethral microwave thermotherapy, transurethral needle ablation of the prostate, urethro microablation phototherapy, and photo selective 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.

### **Summary**

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.

The following conclusions are based on a review of the evidence, including but not limited to, published evidence and clinical expert opinion, solicited via BCBSA's Clinical Input Process.

For individuals who have 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 and receive a PUL, the evidence includes systematic reviews, randomized controlled trials (RCTs), and noncomparative studies. The 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 six 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 two years. PUL was further superior to transurethral resection of the prostate 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 three 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 BPH6 and LIFT RCTs excluded men with median lobe obstruction. The published evidence supports a meaningful improvement in the net health outcome. Evidence reported through clinical input further supports that this use provides a clinically meaningful improvement in net health outcome and is consistent with generally accepted medical practice. Selection criteria of patients for whom evidence is sufficient to support improvement are derived from clinical trial eligibility criteria, product labeling, and clinical input. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

## Policy History

Date	Action
1/2020	BCBSA National medical policy review. Medically necessary statement was updated to remove: Patient does not have prostate-specific antigen level $\geq 3$ ng/ml. Medically necessary criterion regarding nickel allergy was expanded to include titanium and stainless steel. Effective 1/1/2020.
1/2019	BCBSA National medical policy review. The medically necessary statement related to not being a surgical candidate for TURP was removed. Effective 1/1/2019.
6/2018	BCBSA National medical policy review. New medically necessary indications described. Clarified coding information. Effective 6/1/2018.
10/2016	New references added from BCBSA National medical policy.
8/2016	Local Coverage Determination (LCD): Prostatic Urethral Lift (PUL) (L36601) indicating coverage for Medicare members added. Effective 7/1/2016.
1/2016	New medical policy describing investigational indications. Effective 1/1/2016.

## Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

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