Corporate Medical Policy

Prostatic Urethral Lift

File Name: prostatic_urethral_lift
Origination: 10/2015
Last Review: 11/2023

Description of Procedure or Service

Benign prostatic hyperplasia (BPH) is a common condition 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 aged 70 to 79. The clinical manifestations of BPH include increased urinary frequency, nocturia, an 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) is a self-administered 7-item questionnaire assessing the severity of various urinary symptoms. Total AUASI scores range from 0 to 35, with overall severity categorized as mild (≤7), moderate (8-19), or severe (20-35). The International Prostate Symptom Score incorporates the questions from the AUASI and a quality of life question or "Bother score."

Management of BPH

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.

Medical Therapy

A discussion about medical therapy is generally indicated for individuals with moderate-to-severe symptoms (e.g., AUASI score, ≥8), bothersome symptoms, or both. Available medical therapies for BPH-related lower urinary tract dysfunction include α-adrenergic blockers (e.g., alfuzosin, doxazosin, tamsulosin, terazosin, silodosin), 5α-reductase inhibitors (e.g., finasteride, dutasteride), combination α-adrenergic blockers and 5α-reductase inhibitors, anti-muscarinic agents (e.g., darifenacin, solifenacin, oxybutynin), and phosphodiesterase-5 inhibitors (e.g., tadalafil).

Surgical and Ablative Therapies

Individuals 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 (TURP) is generally considered the reference standard for comparisons of BPH procedures. 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, one 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%)." Incidental carcinoma of the prostate was diagnosed by histologic examination in 9.8% of patients. In the longer term, TURP is associated with 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."

Prostatic Urethral Lift (PUL)

The prostatic urethral lift procedure involves placement of one or more implants in 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 (NeoTract, Pleasanton, CA), has clearance 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 1 UroLift implant.

Regulatory Status

One implantable transprostatic tissue retractor system has been cleared for marketing by FDA through the 510(k) process. The NeoTract UroLift System UL400 (NeoTract, Pleasanton, CA) received clearance in December 2013 (after receiving clearance through FDA's de novo classification process in March 2013; K130651/DEN130023). In March 2016, FDA determined that the UL500 was substantially equivalent to existing devices (UL400) for the treatment of symptoms of urinary flow obstruction secondary to benign prostatic hyperplasia in individuals age 50 years and older. In 2017, 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 one contraindication from men with prostate volume of >80 cc to men with prostate volume of >100 cc.

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for the Prostatic Urethral Lift when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore, member benefit language should be reviewed before applying the terms of this medical policy.

When Prostatic Urethral Lift is covered

Use of prostatic urethral lift in individuals with moderate-to-severe lower urinary tract obstruction due to benign prostatic hyperplasia (BPH) may be considered **medically necessary** when ALL of the following criteria are met:

- Individual is not an appropriate candidate for an invasive surgical procedure using general anesthesia, such as transurethral resection of the prostate, or the individual opts to undergo a minimally invasive procedure.
- Individual has persistent or progressive lower urinary tract symptoms or is unable to tolerate medical therapy for BPH, after an appropriate trial period, defined as one month after an alpha-1-adrenergic antagonist or 3 months after a 5-alpha-reductase inhibitor, or has significant side effects or contraindications to medical therapy.
- Prostate gland volume is estimated to be ≤80 cc, by ultrasound or other radiological assessment.
- The individual is 45 years of age or older.
- Prostate anatomy demonstrates normal bladder neck without an obstructive or protruding median lobe.
- Individual has had appropriate testing to exclude diagnosis of prostate cancer.
- Individual does not have a contact dermatitis nickel allergy.
- The prostatic urethral lift device system is used by a physician trained in the specialty of Urology and trained in the prostate urethral lift procedure.

When Prostatic Urethral Lift is not covered

Use of prostatic urethral lift in all other situations is considered investigational when the above criteria are not met.

Repeat use of prostatic urethral lift as a treatment of BPH is considered investigational.

Use of prostatic urethral lift as a treatment of BPH after use of other minimally invasive procedures for BPH (e.g. transurethral water vapor therapy) is considered investigational.

Use of prostatic urethral lift as a treatment of BPH in a patient with a diagnosis of prostate cancer or in a patient who has been previously treated for prostate cancer is considered investigational.

Use of more than 7 implants in the treatment of BPH is considered investigational.

Policy Guidelines

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 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 RTC, 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 six 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 two years. Prostatic urethral lift was further superior to TURP in preserving ejaculatory 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 in the sham group were given the option to have PUL surgery; 80% of the patients 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 included men with prostate volume up to 80 cm^3 and 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 an improvement in the net health outcome.

In 2018, the American Urological Association revised its guideline titled “Surgical Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia”; the 2018 guidelines were most recently amended in 2021 to include the following recommendations and statements related to 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."

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% CI, 4.2 to 6.1) and 11.9% (95% CI, 10.1 to 13.6), respectively, following an initial PUL. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: *52441, 52442, C9739, C9740*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

American Urological Association (AUA). Guideline: Management of Benign Prostatic Hyperplasia. 2010, reaffirmed 2014; http://www.auanet.org/education/guidelines/benign-prostatic-hyperplasia.cfm . Accessed September 11, 2015.

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.151, 8/13/15

Specialty Matched Consultant Advisory Panel 11/2015

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BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.151, 12/14/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.151, 8/9/2018

Specialty Matched Consultant Advisory Panel 11/2018

Foster H.E., Barry M.J., et al. Surgical Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia (2018). American Urological Association. Retrieved at https://www.auanet.org/guidelines/benign-prostatic-hyperplasia/lower-urinary-tract-symptoms-(2018) on January 3, 2019.

United States Food and Drug Administration. Implantable Transprostatic Tissue Retractor System. 510(K) Number: K173087; 12/28/2017. Retrieved at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K173087 on January 3, 2019.

Medical Director review 7/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.151, 8/8/2019

Specialty Matched Consultant Advisory Panel 11/2019

Medical Director Review 4/2020

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.151, 8/13/2020

Specialty Matched Consultant Advisory Panel 11/2020

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.151, 8/12/2021

Specialty Matched Consultant Advisory Panel 11/2021

Lerner LB, McVary, KT, Barry MJ et al: Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia: AUA Guideline part I, initial work-up and medical management. J Urol 2021; 206: 806.

Lerner LB, McVary, KT, Barry MJ et al: Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia: AUA Guideline part II, surgical evaluation and treatment . J Urol 2021; 206: 818.

Specialty Matched Consultant Advisory Panel 11/2022

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Policy Implementation/Update Information

10/30/15 New policy issued. Prostatic urethral lift is considered investigational. (sk)

3/31/17 Reference added. Specialty Matched Consultant Advisory Panel review 11/30/2016. (sk)

7/1/18 Specialty Matched Consultant Advisory Panel review 11/29/2017. Reference added. Policy statement changed to indicate that 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 specified criteria are met. (sk)

1/15/19 References added. Specialty Matched Consultant Advisory Panel review 11/28/2018. 2017 FDA expanded indication added to Regulatory status. Age requirement lowered to 45 years of age. 2018 American Urological Association guideline added to Policy Guidelines. (sk)

7/30/19 Medical Director review. Removed the following from the eighth bulleted statement in When Prostatic Urethral Lift is covered: "does not have prostate-specific antigen level >=3 ng/mL, OR". (sk)

12/10/19 Reference added. Policy Guidelines updated. Coverage criteria statement "Patient has had appropriate screening for prostate cancer within the past year" changed to "Patient has had appropriate testing to exclude diagnosis of prostate cancer". Specialty Matched Consultant Advisory Panel review 11/20/2019. (sk)

4/14/20 Medical Director review. Description section updated. When Covered section updated. Added three additional non covered indications to When Not Covered section. Updated Policy Guidelines. Policy noticed 4/14/2020 for policy effective date 6/23/2020. (sk)

10/13/20 Investigational statements added in the When Not Covered section for use of Urolift in a patient previously treated for prostate cancer, and for use of more than 7 implants. Policy noticed 10/13/2020 for effective date 12/31/2020. (sk)

5/18/21 Reference added. Regulatory Status updated. Specialty Matched Consultant Advisory Panel review 11/18/2020. (sk)

2/8/22 Reference added. Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 11/17/2021. (sk)

5/30/23 Policy review. Policy Guidelines updated. References updated. Specialty Matched Consultant Advisory Panel review 11/16/2022. (sk)

12/29/23 Reference added. Minor edits to Description section. Specialty Matched Consultant Advisory Panel review 11/2023. Medical Director review 11/2023. (rp)