

FEP 7.01.151 Prostatic Urethral Lift

Effective Date: April 15, 2018

Related Policies: None

Prostatic Urethral Lift

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.

FDA REGULATORY STATUS

One implantable transprostatic tissue retractor system has been cleared for marketing by FDA through the 510(k) process. In December 2013, the NeoTract UroLift® System UL400 (NeoTract, Pleasanton, CA) was cleared (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. FDA product code: PEW.

POLICY STATEMENT

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:

- Patient is not an appropriate candidate for a surgical procedure using general anesthesia, such as transurethral resection of the prostate, due to a chronic medical condition including but not limited to cardiopulmonary disease or chronic anticoagulation therapy.
- Patient has persistent or progressive lower urinary tract symptoms or is unable to tolerate medical therapy (α_1 -adrenergic antagonists maximally titrated, 5 α -reductase inhibitors, or combination medication therapy maximally titrated) over a trial period of no less than 6 months.
- Prostate gland volume is ≤ 80 mL.
- Prostate anatomy demonstrates normal bladder neck without an obstructive or protruding median lobe.
- Patient does not have urinary retention, urinary tract infection, or recent prostatitis (within past year).
- Patient does not have prostate-specific antigen level ≥ 3 ng/mL, or has had appropriate testing to exclude diagnosis of prostate cancer.
- Patient does not have a contact dermatitis nickel allergy.

FEP 7.01.151 Prostatic Urethral Lift

Use of prostatic urethral lift in other situations is considered **investigational**.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

RATIONALE

Summary of Evidence

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 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. 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 outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

European Association of Urology

In 2017, the European Association of Urology updated its guidelines on urethral lift implants, giving a grade B recommendation for the use of UroLift in individuals with lower urinary tract symptoms who had prostates less than 70 mL with no middle lobe and were interested in preserving ejaculatory function. It noted that "long term effects have not been evaluated."

National Institute for Health and Care Excellence

In 2014, the National Institute for Health and Care Excellence published interventional procedural guidance on urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia.³⁵ 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 2015, the Institute published a medical technology guidance on the use of UroLift for treating lower urinary tract symptoms of benign prostatic hyperplasia.³⁶ The guidance stated: "the UroLift system is effective in relieving symptoms of benign prostatic hyperplasia" and "the UroLift system should be considered as an alternative to current surgical procedures for use in a day-case setting in individuals

FEP 7.01.151 Prostatic Urethral Lift

with lower urinary tract symptoms of benign prostatic hyperplasia who are aged 50 years and older and who have a prostate of less than 100 ml without an obstructing middle lobe.”

American Urological Association

The 2010 (reaffirmed 2014) American Urological Association guidelines on the management of benign prostatic hyperplasia did not address the prostatic urethral lift procedure.⁶

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES

1. Sarma AV, Wei JT. Clinical practice. Benign prostatic hyperplasia and lower urinary tract symptoms. *N Engl J Med*. Jul 19 2012;367(3):248-257. PMID 22808960
2. Barry MJ, Fowler FJ, Jr., O'Leary MP, et al. The American Urological Association symptom index for benign prostatic hyperplasia. The Measurement Committee of the American Urological Association. *J Urol*. Nov 1992;148(5):1549-1557; discussion 1564. PMID 1279218
3. O'Leary M P. Validity of the "bother score" in the evaluation and treatment of symptomatic benign prostatic hyperplasia. *Rev Urol*. Winter 2005;7(1):1-10. PMID 16985801
4. Djavan B, Marberger M. A meta-analysis on the efficacy and tolerability of alpha1-adrenoceptor antagonists in patients with lower urinary tract symptoms suggestive of benign prostatic obstruction. *Eur Urol*. Jun 1999;36(1):1-13. PMID 10364649
5. McConnell JD, Roehrborn CG, Bautista OM, et al. The long-term effect of doxazosin, finasteride, and combination therapy on the clinical progression of benign prostatic hyperplasia. *N Engl J Med*. Dec 18 2003;349(25):2387-2398. PMID 14681504
6. McVary KT, Roehrborn CG, Avins AL, et al. American Urological Association Guideline: Management of Benign Prostatic Hyperplasia (BPH). 2010 (affirmed 2014); [http://www.auanet.org/guidelines/benign-prostatic-hyperplasia-\(2010-reviewed-and-validity-confirmed-2014\)](http://www.auanet.org/guidelines/benign-prostatic-hyperplasia-(2010-reviewed-and-validity-confirmed-2014)). Accessed November 7, 2017.
7. Reich O, Gratzke C, Bachmann A, et al. Morbidity, mortality and early outcome of transurethral resection of the prostate: a prospective multicenter evaluation of 10,654 patients. *J Urol*. Jul 2008;180(1):246-249. PMID 18499179
8. Sundaram D, Sankaran PK, Raghunath G, et al. Correlation of Prostate Gland Size and Uroflowmetry in Patients with Lower Urinary Tract Symptoms. *J Clin Diagn Res*. May 2017;11(5):AC01-AC04. PMID 28658743
9. Rosen RC, Catania JA, Althof SE, et al. Development and validation of four-item version of Male Sexual Health Questionnaire to assess ejaculatory dysfunction. *Urology*. May 2007;69(5):805-809. PMID 17482908
10. Cappelleri JC, Rosen RC. The Sexual Health Inventory for Men (SHIM): a 5-year review of research and clinical experience. *Int J Impot Res*. Jul-Aug 2005;17(4):307-319. PMID 15875061
11. Barry MJ, Williford WO, Chang Y, et al. Benign prostatic hyperplasia specific health status measures in clinical research: how much change in the American Urological Association symptom index and the benign prostatic hyperplasia impact index is perceptible to patients? *J Urol*. Nov 1995;154(5):1770-1774. PMID 7563343
12. Roehrborn CG, Wilson TH, Black LK. Quantifying the contribution of symptom improvement to satisfaction of men with moderate to severe benign prostatic hyperplasia: 4-year data from the CombAT trial. *J Urol*. May 2012;187(5):1732-1738. PMID 22425127
13. Barry MJ, Fowler FJ, Jr., O'Leary MP, et al. Measuring disease-specific health status in men with benign prostatic hyperplasia. Measurement Committee of The American Urological Association. *Med Care*. Apr 1995;33(4 Suppl):AS145-155. PMID 7536866
14. Perera M, Roberts MJ, Doi SA, et al. Prostatic urethral lift improves urinary symptoms and flow while preserving sexual function for men with benign prostatic hyperplasia: a systematic review and meta-analysis. *Eur Urol*. Apr 2015;67(4):704-713. PMID 25466940
15. Garrido Abad P, Coloma Del Peso A, Sinues Ojas B, et al. Urolift(R), a new minimally invasive treatment for patients with low urinary tract symptoms secondary to BPH. Preliminary results. *Arch Esp Urol*. Jul-Aug 2013;66(6):584-591. PMID 23985459

FEP 7.01.151 Prostatic Urethral Lift

16. Hoffman RM, Monga M, Elliott SP, et al. Microwave thermotherapy for benign prostatic hyperplasia. *Cochrane Database Syst Rev*. Sep 12 2012;9(9):CD004135. PMID 22972068
17. Shore N, Freedman S, Gange S, et al. Prospective multi-center study elucidating patient experience after prostatic urethral lift. *Can J Urol*. Feb 2014;21(1):7094-7101. PMID 24529008
18. McNicholas TA, Woo HH, Chin PT, et al. Minimally invasive prostatic urethral lift: surgical technique and multinational experience. *Eur Urol*. Aug 2013;64(2):292-299. PMID 23357348
19. Chin PT, Bolton DM, Jack G, et al. Prostatic urethral lift: two-year results after treatment for lower urinary tract symptoms secondary to benign prostatic hyperplasia. *Urology*. Jan 2012;79(1):5-11. PMID 22202539
20. Woo HH, Bolton DM, Laborde E, et al. Preservation of sexual function with the prostatic urethral lift: a novel treatment for lower urinary tract symptoms secondary to benign prostatic hyperplasia. *J Sex Med*. Feb 2012;9(2):568-575. PMID 22172161
21. Woo HH, Chin PT, McNicholas TA, et al. Safety and feasibility of the prostatic urethral lift: a novel, minimally invasive treatment for lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH). *BJU Int*. Jul 2011;108(1):82-88. PMID 21554526
22. Cantwell AL, Bogache WK, Richardson SF, et al. Multicentre prospective crossover study of the 'prostatic urethral lift' for the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia. *BJU Int*. Apr 2014;113(4):615-622. PMID 24765680
23. Roehrborn CG, Gange SN, Shore ND, et al. The prostatic urethral lift for the treatment of lower urinary tract symptoms associated with prostate enlargement due to benign prostatic hyperplasia: the L.I.F.T. Study. *J Urol*. Dec 2013;190(6):2161-2167. PMID 23764081
24. McVary KT, Gange SN, Shore ND, et al. Treatment of LUTS secondary to BPH while preserving sexual function: randomized controlled study of prostatic urethral lift. *J Sex Med*. Jan 2014;11(1):279-287. PMID 24119101
25. Roehrborn CG, Rukstalis DB, Barkin J, et al. Three year results of the prostatic urethral L.I.F.T. study. *Can J Urol*. Jun 2015;22(3):7772-7782. PMID 26068624
26. Shore N. A review of the prostatic urethral lift for lower urinary tract symptoms: symptom relief, flow improvement, and preservation of sexual function in men with benign prostatic hyperplasia. *Curr Bladder Dysfunct Rep*. Mar 27 2015;10(2):186-192. PMID 25984251
27. Jones P, Rajkumar GN, Rai BP, et al. Medium-term outcomes of Urolift (minimum 12 months follow-up): evidence from a systematic review. *Urology*. Nov 2016;97:20-24. PMID 27208817
28. Bozkurt A, Karabakan M, Keskin E, et al. Prostatic urethral lift: a new minimally invasive treatment for lower urinary tract symptoms secondary to benign prostatic hyperplasia. *Urol Int*. Nov 2016;96(2):202-206. PMID 26613256
29. Sonksen J, Barber NJ, Speakman MJ, et al. Prospective, randomized, multinational study of prostatic urethral lift versus transurethral resection of the prostate: 12-month results from the BPH6 study. *Eur Urol*. Oct 2015;68(4):643-652. PMID 25937539
30. Ray A, Morgan H, Wilkes A, et al. The Urolift System for the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia: a NICE Medical Technology Guidance. *Appl Health Econ Health Policy*. Oct 2016;14(5):515-526. PMID 26832146
31. Gratzke C, Barber N, Speakman MJ, et al. Prostatic urethral lift vs transurethral resection of the prostate: 2-year results of the BPH6 prospective, multicentre, randomized study. *BJU Int*. May 2017;119(5):767-775. PMID 27862831
32. Roehrborn CG, Barkin J, Gange SN, et al. Five year results of the prospective randomized controlled prostatic urethral L.I.F.T. study. *Can J Urol*. Jun 2017;24(3):8802-8813. PMID 28646935
33. Rukstalis D, Rashid P, Bogache WK, et al. 24-month durability after crossover to the prostatic urethral lift from randomised, blinded sham. *BJU Int*. Oct 2016;118 Suppl 3:14-22. PMID 27684483
34. Roehrborn CG. Prostatic urethral lift: a unique minimally invasive surgical treatment of male lower urinary tract symptoms secondary to benign prostatic hyperplasia. *Urol Clin North Am*. Aug 2016;43(3):357-369. PMID 27476128
35. National Institute for Health and Care Excellence (NICE). Insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia [IPG475]. 2014; <http://www.nice.org.uk/guidance/ipg475/chapter/1-recommendations>. Accessed November 7, 2017.
36. National Institute for Health and Care Excellence (NICE). Urolift for treating lower urinary tract symptoms of benign prostatic hyperplasia [MTG26]. 2015; <https://www.nice.org.uk/guidance/mtg26>. Accessed November 7, 2017.

FEP 7.01.151 Prostatic Urethral Lift

POLICY HISTORY

Date	Action	Description
December 2015	New Policy	
December 2016	Update Policy	Policy updated with literature review through July 10, 2016; references 11, 21-22, 24, 26, and 28 added. Policy statement unchanged.
March 2018	Update Policy	Policy updated with literature review through October 9, 2017; references 4-5, 24, 28-29, and 31 added. 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.

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.