FEP Medical Policy Manual

FEP 7.01.151 Prostatic Urethral Lift

Annual Effective Policy Date: January 1, 2025

Original Policy Date: January 2015

Related Policies:

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

Prostatic Urethral Lift

Description

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.

OBJECTIVE

The objective of this evidence review is to determine whether prostatic urethral lift improves the net health outcome in individuals with benign prostatic hyperplasia.

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:

- The individual has persistent or progressive lower urinary tract symptoms despite medical therapy (α_1-adrenergic antagonists maximally titrated, 5α-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 ≤80 mL; AND,
- Prostate anatomy demonstrates normal bladder neck without an obstructive or protruding median lobe; AND,
- Individual does not have urinary retention related to conditions other than benign prostatic hyperplasia, urinary tract infection, or recent prostatitis (within past year); AND,
- Individual has had appropriate testing to exclude diagnosis of prostate cancer; AND,
- Individual 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**.

POLICY GUIDELINES

Use of temporarily implanted nitinol devices for benign prostatic hyperplasia is addressed separately in evidence review 7.01.175.

BENEFIT APPLICATION

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

FDA 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.

RATIONALE

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^3 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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

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..[7,] 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

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).[49,] 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.[50,] 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."

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

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

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
December 2015	New policy	
December 2016	Replace policy	Policy updated with literature review through July 10, 2016; references 11, 21-22, 24, 26, and 28 added. Policy statement unchanged.
March 2018	Replace 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.
December 2018	Replace policy	Policy updated with literature review through June 4, 2018; references 6 and 37-38 added. The medically necessary statement related to not being a surgical candidate for TURP was removed.
December 2019	Replace policy	Policy updated with literature review through June 19, 2019; references added. The medically necessary (MN) statement was updated to remove the clause 'Patient does not have prostate-specific antigen level - 3 ng/mL' from the fifth criterion. The MN criterion regarding nickle allergy was expanded to include titanium and stainless steel.
December 2020	Replace policy	Policy updated with literature review through July 2, 2020; references added. Repeat procedures explicitly added to the investigational policy statement; statements otherwise unchanged.
December 2021	Replace policy	Policy updated with literature review through July 7, 2021; references added. Policy statements unchanged.
December 2022	Replace policy	Policy updated with literature review through July 7, 2022; references added. Minor editorial refinements to policy statements; intent unchanged
December 2023	Replace policy	Policy updated with literature review through July 7, 2023; reference added. Minor editorial refinements to policy statements; intent unchanged.
December 2024	Replace policy	Policy updated with literature review through June 14, 2024; reference added. Policy statements unchanged.