FEP Medical Policy Manual

FEP 7.01.151 Prostatic Urethral Lift

Effective Policy Date: January 1, 2020

Original Policy Date: January 2015

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.

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 patient 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,
- 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**.

POLICY GUIDELINES

None

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 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. FDA product code: PEW.

RATIONALE

Summary of Evidence

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 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 prosthetic urethral lift (PUL), the evidence includes systematic reviews, randomized control trials (RCTs), and non-comparative studies. The relevant outcomes are symptoms, functional outcomes, health status measures, quality of life (QOL), 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 non-inferior 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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (2014) published guidance on urethral lift implants to treat lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH).[38] 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."

The Institute (2015) published guidance on the use of UroLift for treating LUTS of BPH.[39] 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 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 American Urological Association (2018) published guidelines on the surgical management of LUTS attributed to BPH; the 2018 guidelines were amended in 2019.[6,40,41] The guidelines made the following recommendations and statements regarding prostatic urethral lift (PUL).

- "Clinicians should consider PUL [prostatic urethral lift] as an option for patients with LUTS [lower urinary tract symptoms] attributed to BPH [benign prostatic hyperplasia] provided prostate volume <80g and verified absence of an obstructive middle lobe; however, patients should be informed that symptom reduction and flow rate improvement is less significant compared to TURP [transurethral resection of the prostate]. Patients should be informed that evidence of efficacy and retreatment rates are poorly defined. "
    - "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"
    - "...the quality of evidence for non-serious harms related to the procedure was rated low, while that for incontinence, need for reoperation, and serious harms related to treatment was rated very low."
    - "...patients selecting PUL should be informed that this is a relatively new intervention for LUTS/BPH with uncertainties in long-term durability, though such uncontrolled data are available."
- "PUL may be offered to eligible patients concerned with erectile and ejaculatory function for the treatment of with LUTS attributed to BPH."
    - "Conditional Recommendation; Evidence Level: Grade C indicating "Risks/Burdens unclear; Alternative strategies may be equally reasonable. Better evidence likely to change confidence"

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.