Medical Policies - Surgery

Prostatic Urethral Lift (PUL) for the treatment of Benign Prostatic Hyperplasia (BPH)

Number: SUR710.023

Effective Date: 12-01-2015

Coverage:

The UroLift system may be considered medically necessary for treatment of lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH) when ALL of the following criteria are met:

• Age 50 years or older; AND
• Prostate size no greater than 80 grams based on ultrasound imaging; AND
• International Prostate System Score (IPSS) ≥ 13; AND
• Peak flow rate (Qmax) ≤ 12mL/second; AND
• No obstructive median lobe; AND
• No active urinary tract infection; AND
• Conservative management options have been unsuccessful; AND
• Surgical intervention is indicated.

Description:

Benign Prostatic Hyperplasia

Benign prostatic hyperplasia (BPH) is a common disorder among older men 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 men aged 70 to 79. (1) The clinical manifestations of BPH include increased urinary frequency, urgency, nocturia, hesitancy, and weak stream. 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. (2) 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.” (3)

**Management of BPH**

Evaluation and management of BPH includes evaluation for other causes of lower urinary tract dysfunction (e.g., prostate cancer). Symptom severity and the degree that symptoms are bothersome determine the therapeutic approach.

**Medical Therapy**

A discussion about medical therapy is generally indicated for patients 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). (1)

**Surgical and 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 treatments. (4) 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, a 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%).”5 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 have also been developed, including transurethral microwave thermotherapy, transurethral needle ablation of the prostate, urethromicroablation phototherapy, and photoselective vaporization of the prostate.

**Prostatic Urethral Lift**

The prostatic urethral lift procedure involves placement of 1 or more implants in the lateral 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. The device has 2 main components: the delivery device and the implant. Each delivery device comes preloaded with 1 UroLift implant.

**Outcome Measures Used in Evaluating BPH Symptoms**

A number of health status measures are used to evaluate symptoms relevant to BPH and adverse effects of treatment for BPH, including urinary dysfunction, ejaculatory dysfunction, overall sexual health, and overall quality of life. Some validated scales are shown in Table 1.

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<thead>
<tr>
<th>Measure</th>
<th>Outcome Evaluated</th>
<th>Description</th>
<th>Clinically Meaningful</th>
</tr>
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<tbody>
<tr>
<td>Male Sexual Health Questionnaire for Ejaculatory Dysfunction (MSHQ-EjD) (6)</td>
<td>Ejaculatory function</td>
<td>Patient-administered, 4-item scale</td>
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Table 1: Health Status Measure Relevant to Benign Prostatic Hyperplasia
| Sexual Health Inventory for Men (SHIM) (7) | Erectile function | Patient-administered, 5-item scale; final score range, 1 (worst symptoms) to 25 (fewest symptoms) | Minimum of 3-point Change (1,8) |
| International Prostate Symptom Score (IPSS) (3) | Severity of lower urinary tract Symptoms | Patient-administered, 8-item scale | |
| Benign Prostatic Hyperplasia Impact Index (BPH-II) (9,4) | Effect of urinary symptoms on health domains | Patient-administered, 4-item scale; final score range, 0 (best) to 13 (worst) | Minimum of 0.4-point Change (8) |

One implantable transprostatic tissue retractor system has been cleared for marketing by FDA through the 510(k) process. The NeoTract UroLift System (NeoTract, Pleasanton, CA) received clearance in December 2013 (after receiving clearance through FDA’s de novo classification process in March 2013; K130651/DEN130023). The UroLift System is intended for the treatment of symptoms of urinary flow obstruction secondary to benign prostatic hyperplasia in men age 50 years and older. FDA product code: PEW.

**Rationale:**

This policy was originally developed in June of 2015 and has been updated with searches of scientific literature through September 2015. This section of the current policy has been substantially revised. The following is a summary of the key literature to date.

**Randomized Controlled Trials**

BPH6 Study
In 2015, Sonksen et al. reported results of a multicenter RCT comparing the prostatic urethral lift procedure with TURP among men aged 50 and over with lower urinary tract symptoms secondary to benign prostatic obstruction. (10) Eligible patients had an International Prostate Symptom Score (IPSS) above 12, a peak urinary flow rate (Qmax) of 15 mL/s or less for a 125-mL voided volume, a post void residual volume less than 350 mL, and prostate volume of 60 cm3 or less on ultrasound. The study used a novel composite end point, referred to as the BPH6, which included lower urinary tract symptom relief measured by the IPSS score, recovery experience measured on a visual analog scale (VAS), erectile function measured by the Sexual Health Inventory for Men (SHIM) scale, ejaculatory function measured by the Male Sexual Health Questionnaire for Ejaculatory Dysfunction (MSHQ-EjD), continence preservation measured by the Incontinence Severity Index (ISI), and safety measured by no treatment related adverse event greater than grade 1 on the Clavien-Dindo classification system. Patients were considered treatment responders if they met all 6 composite criteria. The study used a noninferiority design with a margin of 10% for the BPH6 primary end point. Study investigators modified 2 of the original end point definitions in the study’s analysis, including changing the sexual function element assessment from a single time point (12 months) to assess sustained effects during 12 months of follow-up, and lowering the threshold of quality of recovery on VAS from 80 to 70.

Ninety-one patients were randomized to (n=45) or prostatic urethral lift (n=46). Ten patients in the TURP group and 1 patient in the prostatic urethral lift group declined treatment, leaving an analysis group of 80 subjects. Analysis was per-protocol; including 35 in the TURP group and 44 in the prostatic urethral group (1 patient was excluded for violation of the active urinary retention exclusion criterion). Groups were similar at baseline, with the exception of MSHQ-EjD Function score. For procedure recovery, 82% of the prostatic urethral lift group achieved the recovery end point by 1 month compared with 53% of the TURP group (p=0.008). For the study’s primary outcome, the proportion of participants who met the original BPH6 primary end point was 34.9% for the prostatic urethral lift group and 8.6% for the TURP group (noninferiority p<0.001; superiority p=0.006). The modified BPH6 primary end point was met by 52.3% of the prostatic urethral lift group and 20.0% of the TURP group (noninferiority p<0.001; superiority p=0.005). Both groups demonstrated improvements over IPSS, IPSS Quality of Life score, Benign Prostatic Hyperplasia Impact Index (BPH-II) score, and Qmax
over time. IPSS, Qmax, and post void residual volumes were better for the TURP group than the prostatic urethral lift group. The TURP group demonstrated declines in ejaculatory function (average MSHQ-EjD score) compared with baseline (9 at baseline vs 5.6 at 12-month follow-up; p<0.001), while the prostatic urethral lift group demonstrated a slight improvement (11 at baseline vs 11.9 at 12-month follow-up, p=0.03) for an overall difference between groups of -5.0 (95% confidence interval [CI], -6.9 to -3.1; p<0.001).

LIFT Study

In 2013, Roehrborn et al. reported results of the pivotal LIFT study, an RCT comparing prostatic urethral lift with sham control among 206 men aged 50 and older with lower urinary tract symptoms secondary to BPH. (11) Eligible patients had an American Urological Association Symptom Index (AUASI) of 13 or greater, Qmax of 12 mL/s or less for a 125-mL voided volume, and a prostate volume between 30 and 80 mL. Patients were randomized to prostatic urethral lift (n=140) or sham control (n=66) and evaluated at 3 months post procedure for the study’s primary efficacy end point. After that, all patients were unblended and sham control patients were permitted to undergo the prostatic urethral lift procedure. Fifty-three control subjects eventually underwent a prostatic urethral lift procedure. Analysis was intention-to-treat. The study met its primary efficacy end point that the reduction in AUASI score at 3 months post procedure was at least 25% greater after the prostatic urethral lift than that seen with sham (p=0.003). The AUASI score decreased from 24.4 at baseline to 18.5 at 3-month follow-up for sham control patients and from 22.2 at baseline to 11.2 at 3-month follow-up for prostatic urethral lift patients. The 3-month change in Qmax was 4.28 mL/s for prostatic urethral lift patients and 1.98 mL/s for sham control patients (p=0.005). Compared with sham control patients, prostatic urethral lift patients had greater decreases in quality of life scores (note that specific quality of life scoring device was not specified) and BPH-II score.

McVary et al. reported on sexual function outcomes in a subset of patients from the LIFT study. (12) At baseline, 53 (38%) prostatic urethral lift subjects and 23 (53%) sham control subjects were sexually inactive or had severe erectile dysfunction and were censored from the primary sexual function analysis. Scores on the SHIM and MSHQ-EjD Function scale and the MSHQ- EjD Bother scale did not differ significantly between groups.
In 2014, Cantwell et al. reported on the outcomes for the 53 subjects in the LIFT sham control group who underwent prostatic urethral lift after unblinding at 3 months post procedure. (13) Crossover (unblinded) patients had a change in IPSS score from 23.4 to 12.3 at 3 months post procedure compared with the change in IPSS score from 25.2 to 20.2 at 3 months after the sham procedure. Subjects had greater improvements in BPH-II score in the crossover period than in the sham period (-3.3 vs -1.9, p=0.024), but did not have significant differences in improvement in Qmax. Change in sexual function scores did not differ significantly after sham procedure compared with after active procedure.

In 2015, Roehrborn et al. reported 3-year results from patients randomized to prostatic urethral lift in the LIFT study. (14) After exclusion of 11 subjects who were lost to follow-up, 36 subjects who either had missing data, protocol deviations, medication treatment for benign prostatic hyperplasia (BPH), or other prostate procedures, and 15 subjects who underwent surgical retreatment for lower urinary tract symptoms (6 with repeat prostatic urethral lift procedures, 9 with TURP or laser vaporization), the 3-year effectiveness analysis included 93 subjects. For subjects included in the follow-up data, change in IPSS score was -8.83 (95% CI, -10.35 to -7.30, p<0.001). Significant improvements were also reported for quality of life score, BPH-II score, and Qmax. Sexual function was unchanged. Implants were removed from 10 participants.

Additional Studies

Other non-comparative studies described outcomes after the prostatic urethral lift procedure in sample sizes ranging from 19 to 102. (15-19) The study reporting the longest follow-up was by Chin et al., which reported outcomes for 64 men at 6 Australian institutions up to 24 months post procedure. (15) At the time of publication, 33 patients had reached 24 months of follow-up. At 24 months, patients had an improvement in IPSS score of -9.2 compared with baseline. Other outcome parameters, including quality of life scores, BPH-II score, and Qmax, had similar magnitudes of improvement at 24 months immediately post procedure.

In 2015, Perera et al. reported results of a systematic review and meta-analysis (20) of studies reporting outcomes after the prostatic urethral lift procedure, which included 7 prospective cohort studies, 1 crossover study (Cantwell et al.), (13) and the LIFT RCT (Reorhborn et al., (11) McVary et al. (12). The pooled
standardized mean gain (SMG) estimates for prostate symptoms scores (IPSS and BPH-II) and sexual health scores used responses from 452 to 680 patients. SMG for prostatic symptoms scores ranged from -1.3 (95% CI, -1.4 to -1.2) and -1.6 (95% CI, -1.7 to -1.3), which translated into a clinically meaningful improvement. The SGM for sexual health scores ranged from 0.3 (95% CI, 0.2 to 0.4) to 0.4 (95% CI, 0.3 to 0.5), suggesting a small improvement.

Practice Guidelines and Position Statements

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. (21) These guidelines state: "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 provided that normal arrangements are in place for clinical governance, consent and audit."

American Urological Association (AUA)

The 2010 (reaffirmed 2014) American Urological Association guideline on the management of BPH does not address the prostatic urethral lift procedure. (22). However, the AUA noted the following on their website in 2015: “The most current American Urological Association Guideline: Management of Benign Prostatic Hyperplasia (BPH) (originally published in 2010) was reviewed and validity confirmed in 2014 and does not mention the Urolift® procedure as a treatment for BPH. Because literature on new technologies may not be available for review during the stringent AUA guidelines development process, the following disclaimer statement is included in the Guideline addressing this possibility. “Although guidelines are intended to encourage best practices and potentially encompass available technologies with sufficient data as of close of the literature review, they are necessarily time-limited. Guidelines cannot include evaluation of all data on emerging technologies or management, including those that are FDA-approved, which may immediately come to represent accepted clinical practices. For this reason, the AUA does not regard technologies or management which are too new to be addressed by this guideline as necessarily experimental or investigational.” The AUA also notes that Urolift should not be considered investigational but an appropriate therapeutic tool.
used by urologists. They note “The clinical effectiveness has been proven by virtue of going through the Current Procedural Terminology (CPT) approval process”.

The Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)

The SUFU (23) notes the following in a 2015 document addressing the urethral lift procedure: “While most men are well served with medication, many men still require surgical intervention due to lack of an adequate response to pharmacologic management. Of those men requiring intervention, a selected group will benefit from the prostatic urethral lift procedure as a less invasive option that can preserve their bladder health while not risking sexual dysfunction or incontinence. SUFU finds the prostatic urethral lift procedure to be a well-studied, medically necessary option for our patients suffering from BPH. It has been approved by the FDA and we do not consider it to be investigational.”

Summary of Evidence

The evidence for prostatic urethral lift in patients with lower urinary tract obstruction symptoms due to BPH includes 2 randomized controlled trials (RCTs) and a number of non-comparative studies. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, and treatment related morbidity. The LIFT trial reported that the prostatic urethral lift procedure is associated with greater improvements in lower urinary tract symptoms than medical management, without worsened sexual function. One publication from this trial reported that functional improvements were durable over a 3-year follow-up in a subset of patients. Another RCT compared the prostatic urethral lift procedure with transurethral resection of the prostate (TURP) and reported that the prostatic urethral lift was noninferior for the study’s composite end point, which included multiple measures of symptoms and complications combined into a single score. While TURP was associated with greater improvements in urinary tract obstruction symptom outcomes, it was also associated with greater declines in sexual function than the prostatic urethral lift.

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CODING:

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Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member’s benefit contract or Summary Plan Description ( SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

<table>
<thead>
<tr>
<th>CPT/HCPCS/ICD-9/ICD-10 Codes</th>
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<tbody>
<tr>
<td>The following codes may be applicable to this Medical policy and may not be all inclusive.</td>
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<tr>
<td>CPT Codes</td>
</tr>
<tr>
<td>52441, 52442</td>
</tr>
<tr>
<td>HCPCS Codes</td>
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<tr>
<td>C9739, C9740</td>
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<tr>
<td>ICD-9 Diagnosis Codes</td>
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<tr>
<td>Refer to the ICD-9-CM manual</td>
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<td>ICD-9 Procedure Codes</td>
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</tr>
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Medicare Coverage:

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A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare’s National Coverage at <http://www.cms.hhs.gov>.

References:


Policy History:

Date          Reason
12/1/2015 Document updated with literature review. The coverage position was changed to consider the UroLift system medically necessary for the treatment of lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH) when meeting all the following criteria: men age 50 and older, prostate sizes no greater than 80 grams per ultrasound, international prostate symptom score ≥ 13, peak flow rate (Qmax) ≤ 12mLs, no obstructive median lobe, no active urinary tract infection, when conservative management options have been unsuccessful, or are not appropriate, and when surgical intervention is indicated.

6/15/2015 New medical document. Prostatic urethral lift (PUL) for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH), including but not limited to the use of the UroLift® System (transprostatic permanent delivery device and implant), is considered experimental, investigational and/or unproven.

Archived Document(s):

<table>
<thead>
<tr>
<th>Title:</th>
<th>Effective Date:</th>
<th>End Date:</th>
</tr>
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</table>

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