

DRAFT Medical Coverage Policy | Prostatic Urethral Lift



EFFECTIVE DATE:01/01/2017

POLICY LAST UPDATED:

OVERVIEW

Benign prostatic hyperplasia is a common condition in older men that can lead to increased urinary frequency, urgency, nocturia, hesitancy, and weak urinary stream. The prostatic urethral lift (PUL) procedure involves the insertion of 1 or more permanent implants into the prostate, which retract prostatic tissue and maintain an expanded urethral lumen.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Blue CHiP for Medicare

The prostatic urethral lift procedure is considered medically necessary when used for the treatment of symptomatic BPH in a beneficiary with well documented voiding symptoms consistent with prostatic hypertrophy and is a poor candidate for other surgical interventions for BPH due to underlying disease (e.g. cardiac disease, pulmonary disease, etc.) and/or at high risk of bleeding and/or the beneficiary has opted for PUL based on likelihood of preserving sexual function and/or there is another documented reason for opting for PUL.

Commercial Products

The prostatic urethral lift procedure is considered not medically necessary for all indications as the evidence is insufficient to determine the effects of the technology on health outcomes

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable not medically necessary benefits/coverage.

BACKGROUND

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 ages 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.

Prostatic Urethral Lift

The prostatic urethral lift (PUL) 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.

For individuals who have lower urinary tract obstruction symptoms due to benign prostatic hyperplasia who receive 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. The LIFT study was an RCT comparing PUL with sham control that reported the PUL 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 3- and 4-year follow-ups in a subset of patients, but this conclusion is limited because only treated patients were included in the longer follow-up and there was a high loss to follow-up in the treated group. Another RCT, the BPH6 study, compared the PUL procedure with transurethral resection of the prostate (TURP) and reported that PUL 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 PUL. This small trial was limited by unequal dropout rates between groups after enrollment, and uncertainty about the validity of its primary composite outcome measure. The composite measure was composed mostly of safety items, and may have therefore favored the PUL group. Because of limitations with the BPH6 trial, its results do not definitively demonstrate the noninferiority of PUL to TURP; more evidence is needed to corroborate these results. In addition, follow-up in the available studies was inadequate to identify longer term adverse events. The evidence is insufficient to determine the effects of the technology on health outcomes

One device, the NeoTract UroLift System, has been cleared for marketing by the U.S. Food and Drug Administration (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.

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 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 men age 50 years and older. FDA product code: PEW

Blue CHiP for Medicare

Guidance from the National Institute for Health and Clinical Excellence (NICE, 2014) states: "Current evidence on the efficacy and safety of insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to BPH is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit."

Based on this review of literature and guidelines as well as comments received from specialists in the field NGS has determined that Medicare coverage is available when certain criteria are met. These criteria are derived, in part, from the inclusion criteria of the comparative clinical trials and include a requirement that there be a beneficiary specific reason for choosing PUL instead of TURP or other tissue destructive approach. Beneficiary specific reasons for choosing PUL include comorbid medical illness which increases the risk associated with TURP, risk of bleeding rendering a less invasive approach preferred, or a beneficiary's desire to maintain sexual function (since the clinical trials have shown an advantage in this regard).

Indications:

NGS considers prostatic urethral lift procedures reasonable and necessary when the ALL of the following criteria are met:

- The UroLift device is used for the treatment of symptomatic BPH in a beneficiary with well documented voiding symptoms consistent with prostatic hypertrophy; and
- AUA symptom index (AUASI) score greater than or equal to 13; and

- Peak urine flow rate (Q_{max}) less than or equal to 12 cc/sec on a voided volume that is greater than 125 cc; and
- The beneficiary has had an adequate trial of, but is refractory to or intolerant of, usual BPH medication; and
- The prostate volume is less than or equal to 80 cc without an obstructive median lobe; and
- There are no signs, symptoms, or diagnostic evidence of an active urinary infection and no history of bacterial prostatitis in the past three (3) months; and
- The beneficiary is a poor candidate for other surgical interventions for BPH due to underlying disease (e.g. cardiac disease, pulmonary disease, etc.) and/or at high risk of bleeding and/or the beneficiary has opted for PUL based on likelihood of preserving sexual function and/or there is another documented reason for opting for PUL.
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CODING

The following codes are covered for Blue CHiP for Medicare and not medically necessary for Commercial Products:

52441 Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant
 52442 each additional permanent adjustable transprostatic implant (List separately in addition to code for primary procedure)

The following codes will deny as use alternate code as claims should be filed with one of the above CPT codes.

C9739 Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants
 C9740 Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants

RELATED POLICIES

None

PUBLISHED

Provider Update, November 2016

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