

Molina Clinical Policy

Prostatic Urethral Lift or UroLift for Benign Prostatic Hyperplasia (BPH): Policy No. 250

Last Approval: 8/9/2023

Next Review Due By: August 2024



DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

The prostatic urethral lift (PUL) or UroLift System is a minimally invasive technology for treating lower urinary tract symptoms due to benign prostatic hyperplasia (BPH). The UroLift is a permanent implant that is inserted during a minimally invasive transurethral outpatient procedure proposed to relieve prostate obstruction and open the urethra directly leaving the prostate intact (McVary 2021). The PUL procedure consists of small permanent transprostatic implants placed cystoscopically to compress the prostate tissue, therefore increasing the urethral lumen and reducing obstruction to urine flow (Hayes 2023; McVary 2021). Subsequently, 4 or 5 implants are delivered into the prostatic urethra to maintain urethral patency. A final cystoscopy confirms that the implants were appropriately positioned. Most common adverse events reported include hematuria, dysuria, micturition urgency, pelvic pain, and urge incontinence (Hayes 2023).

On September 13, 2013, the Food and Drug Administration (FDA) approved the UroLift for marketing through a de novo classification as a class II device used as a permanent implant to relieve low or blocked urine flow in men aged 50 and older with benign prostatic hyperplasia (BPH). According to the FDA The UroLift System should not be used if the patient has any of the following conditions (FDA 2019 & 2013):

- Prostate volume of >80 cc
- An obstructive or protruding median lobe of the prostate
- A urinary tract infection
- Urethra conditions that may prevent insertion of delivery system into bladder
- Urinary incontinence
- Current gross hematuria
- A known allergy to nickel

Subsequent clearances of the UroLift System have been made based on substantial equivalence to the original device. In 2019, the FDA expanded the indications to include the treatment of symptoms due to urinary outflow obstruction secondary to BPH, including lateral and median lobe hyperplasia, in men 45 years of age or older. The FDA also amended the contraindications from "men with Prostate volume of >80 cc" to "men with Prostate volume of >100 cc".

The UroLift 2 System received FDA approval on July 31, 2020 (FDA 2020). The indications and contraindications remain the same as the UroLift System FDA clearance in 2019.

COVERAGE POLICY

The Prostatic Urethral Lift or UroLift for individuals with symptomatic Benign Prostatic Hyperplasia (BPH) **may be considered medically necessary** when **ALL** of the following criteria are met:

1. Age \geq 45 years; **AND**

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2. Diagnosis of moderate to severe BPH defined by the American Urological Association (AUA) with a symptom score above 7 with signs of obstruction that include **EITHER** of the following:
 - a. increased voiding symptoms; **OR**
 - b. decreased peak urinary flow rate (e.g., a peak urine flow rate (Qmax) less than 15 cc/sec on a voided volume that is greater than 125 cc).

AND

3. Refractory to or intolerant of standard BPH medication; **AND**
4. Enlarged lateral lobes without an obstructive median lobe; **AND**
5. Prostatic volume less than or equal to 100 cc; **AND**
6. No active urinary infection; **AND**
7. Normal renal function; **AND**
8. No allergy to nickel.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

There is sufficient published evidence to assess the role of the PUL (or UroLift) for the treatment of patients with for benign prostatic hyperplasia. This is a minimally invasive alternative to drug therapy and/or surgery and may be a viable alternative for men requiring require surgical therapy for BPH due to medically refractory symptoms.

Franco et al. (2021) completed a network meta-analysis to determine the effectiveness of minimally invasive treatments for lower urinary tract symptoms (LUTS) in men with BPH. The meta-analysis included 27 studies with a total of 3017 men with severe LUTS. The procedures analyzed included PUL, prostatic arterial embolization, convective radiofrequency water vapor therapy, and transurethral microwave thermotherapy. The three primary outcomes were urinary symptoms, urinary quality of life, and adverse effects of each treatment compared to a traditional surgical approach. Results specific to PUL showed that PUL may result in little or no difference in urologic symptoms or quality of life compared to transurethral prostate resection (TURP). However, PUL may significantly reduce the risk of major adverse events. PUL was noted to have better rankings for symptoms scores and fewer retreatments compared to TURP. There was uncertainty regarding the effects of PUL on erectile and ejaculatory function.

Xiang et al. (2020) completed a systematic review and meta-analysis to synthesize the current evidence for PUL. The analysis included 19 studies with a total of 605 patients that had undergone the PUL procedure. The outcomes measured were International Prostate Symptom Score (IPSS), Benign Prostatic Hyperplasia Impact Index (BPHII), quality of life, Qmax, and post-void residual volume (PVR). IPSS scores are based on 8 questions related to symptoms of BPH and scores can range from 0-35 with higher numbers representing more severe symptoms. BPHII scores are based on 4 questions related to the impact of urinary symptoms due to BPH and scores can range from 0-13 with higher scores indicating a more significant impact on quality of life. Results showed pooled IPSS score decreases after PUL procedure of -10.97 [-12.44 to -9.51] at 1-1.5 months, -12.16 [-13.64 to -10.68] at 3-4 months, -11.09 [-12.51 to -9.68] at 6 months, -10.45 [-11.70 to -9.20] at 12 months, and -9.73 [-10.77 to -8.69] at 24 months. Pooled BPHII score decreases after PUL were -3.74 [-4.45 to -3.03] at 1-1.5 months, -4.46 [5.16 to -3.75] at 3-4 months, -4.50 [-5.22 to -3.97] at 6 months, -4.37 [-5.08 to -3.65] at 12 months, and -3.90 [-4.46 to -3.35] at 24 months. Mean quality of life scores improved by 2.20 to 2.55. The pooled Qmax improved from 3.44ml/s to 4.26ml/s. The pooled PVR following PUL was 2.53ml [-21.62 to 26.68] at 1-1.5 months, -31.33ml [-64.71 to 2.06] at 6 months, -14.84ml [-31.08 to 1.40] at 12 months, and -11.22ml [-26.16 to 3.72] at 24 months. Complications occurred early, were mild, and required no special treatment. The most common complications reported were dysuria (9.09-52.9%), hematuria (2.64-74.5%), pelvic pain (0-52.3%), urinary tract infection (0.98-10.9%), and incontinence (0-7.81%). Complications were unable to be compared statistically due to the usage of different definitions and terms in each study. Researchers determined that PUL can relieve prostatic symptoms for 24 months without serious complications while also preserving or slightly improving sexual function. Approximately 3.57-18.8% of patients progressed to TURP within 24 months.

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Miller et al. (2020) completed a systematic review and meta-analysis to determine the surgical reintervention rate after PUL. Included studies had to have a minimum of one year follow-up after PUL procedure. A total of 11 studies were included with a total of 2016 patients. A total of 153 surgical reinterventions were performed with the most common being TURP (51.0%), repeat PUL (32.7%), and device explant (19.6%). The median reintervention rate per year was 6.0% with the rate being affected by longer follow-up periods. Studies with a mean follow-up period of 1 year had a reintervention rate of 4.3% per year while studies with 1-3 years of mean follow-up had a reintervention rate of 10.7% per year. Studies with a mean follow-up period of greater than 3 years had a reintervention rate of 5.8% per year. The overall mean surgical reintervention rate was 6.0%.

National and Specialty Organizations

NICE published a 2022 update to its 2021 guidance with continued recommendation for UroLift based on a larger body of published clinical evidence. NICE notes that the UroLift is not as effective as TURP. However, it is recommended as a less invasive option with fewer complications for those over 50 years of age and a prostate volume of 30-80 mL (Knight et al. 2022).

The **American Urological Association (AUA)** indicates that the PUL should be considered as a treatment option for patients with LUTS/BPH provided prostate volume 30-80cc and verified absence of an obstructive middle lobe. (Moderate Recommendation; Evidence Level: Grade C). The AUA also states that 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). (¹⁻² Lerner et al. 2021)

The **National Institute for Health and Clinical Excellence (NICE)** (2021) indicates that the UroLift System is a minimally invasive procedure, which 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.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Codes

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

HCPCS (Healthcare Common Procedure Coding System) Codes

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

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

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|-----------|--|
| 8/9/2023 | Policy reviewed, no changes to coverage criteria. Updated Overview, Summary of Medical Evidence, and References sections. Grammatical edits to Disclaimer section and Documentation Requirements disclaimer. Removed Supplemental Information section. |
| 8/10/2022 | Policy reviewed, no changes to coverage criteria. Updated Summary of Medical Evidence and Reference sections. |
| 8/11/2021 | Policy reviewed, clinical criteria changed based on new FDA guidance (age changed to >45 years; prostatic volume (from 80cc ≤ 100 cc; added updated FDA indications). Updated guidelines, references. Policy reviewed in June 2021 by an AMR practicing, |

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board-certified physician in the area of Urology.

9/18/2019 & 9/16/2020 Policy reviewed, no changes, updated references, added TOC.

3/8/2018 Policy reviewed and updated from investigational status to medically necessary based on newly published evidence. Summary of Medical Evidence (and references) updated with professional guidelines.

12/16/2015, 12/14/2016 & 6/22/2017 Policy reviewed, no changes.

6/2/2015 New policy.

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APPENDIX

Reserved for State specific information. Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.