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

Last Approval: 08/14/2024
Next Review Due By: August 2025

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 2024). 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 2024). 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).

Regulatory Status

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).

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 (K201837) received FDA approval on July 31, 2020 (FDA 2020). The indications and contraindications remain the same as the UroLift System FDA clearance in 2019.

The UroLift 2 ATC Advanced Tissue Control System (K232558) received FDA approval on September 22, 2023. “The primary difference is the addition of a wing component on the distal tip of the UroLift 2 ATC Advanced Tissue Control System which provides a larger footprint during the procedure and allowing for effective mobilization of tissue when needed. The remainder of the device is substantially equivalent to the UroLift 2 System UroLift 2 ATC Advanced Tissue Control System is indicated for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH), including lateral and median lobe hyperplasia.”
According to the FDA the UroLift 2 System and the UroLift 2 ATC Advanced Tissue Control System should not be used if the patient has:

- Prostate volume of >100 cc
- A urinary tract infection
- Urethra conditions that may prevent insertion of delivery system into bladder
- Urinary incontinence due to incompetent sphincter
- Current gross hematuria

COVERAGE POLICY

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

1. Age ≥ 45 years
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
   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)
3. Refractory to or intolerant of standard BPH medication
4. Lateral and/or median lobe hyperplasia
5. Prostatic volume less than or equal to 100 cc
6. No active urinary infection
7. Normal renal function

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

The L.I.F.T study was a multicenter, randomized controlled blinded study RCT that randomized 206 participants with lateral lobe (LL) obstruction to PUL (n=140) or sham procedure with rigid cystoscopy (n=66). Both the patient and assessor where blinded to the randomization at the three-month endpoint, after which the patients were unblinded. PUL patients were followed for 5 years. Key outcomes measures assessed were International Prostate Symptom Score (IPSS); quality of life (QOL); Qmax = peak flow rate; and BPH Impact Index (BPHII). This minimally invasive procedure did not have the serious side effects of traditional surgery and over the 5-year follow, and up was shown to have sustained symptom improvement in the key indicators of (36% IPSS), quality of life (50% QOL; 52% BPHII) and urinary flow rate (44% Qmax) and an acceptably low surgical retreatment rate of 2%-3% per year (Roehrborn et al. 2017).

The MedLift study was a single arm controlled clinical trial that evaluated post PUL outcomes in men that had an obstructive median lobe and met the criteria of the LIFT study for an obstructed lateral lobe (n=45). MedLift utilized the sham subjects from L.I.F.T as controls for PUL obstructive median lobe treatment. Patients were followed for 12 months post procedure. The MedLift study found that that use of the PUL procedure for patients with OML are similar to those of PUL for LL obstructions, with significant and sustained improvements International Prostate Symptom Score (IPSS); quality of life (QOL); Qmax = peak flow rate; and BPH Impact Index (BPHII) (Rukstalis 2019).

The BPH6 study was an RCT that enrolled 80 BPH patients to compare outcomes for PUL to TURP. 35 men were randomized to a TURP procedure (n=35). Over the 2 year follow up, both arms showed improvement in International Prostate Symptom Score (IPSS), quality of life (QOL); Qmax = peak flow rate; and BPH Impact Index (BPHII). The proportion of patients who met the BPH6 primary endpoint was found to favor PUL vs TURP (non-inferiority P = 0.0002, superiority P = 0.006) (Gratzke et al. 2017).

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.

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, Sandu et al. 2023).

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

Code	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

Code	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

08/14/2024	Policy reviewed. Coverage criteria changed based on FDA indications for use to include patients with median lobe hyperplasia. Removed nickel allergy. Updated Overview, Summary of Medical Evidence, and References sections. IRO Peer Review on July 25, 2024, by a practicing physician board-certified in Urology.
08/09/2023	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.
08/10/2022	Policy reviewed, no changes to coverage criteria. Updated Summary of Medical Evidence and Reference sections.
08/11/2021	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, board-certified physician in the area of Urology.
09/18/2019	Policy reviewed, no changes, updated references**.**
09/16/2020	Policy reviewed, no changes, updated references, added TOC.
03/08/2018	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	Policy reviewed, no changes.
12/14/2016	Policy reviewed, no changes.
06/22/2017	Policy reviewed, no changes.
06/02/2015	New policy.

REFERENCES

1. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database. Accessed July 22, 2024. https://www.cms.gov/medicare-coverage-database/search.aspx.
2. Franco JV, Jung JH, Imamura M, et al. Minimally invasive treatments for lower urinary tract symptoms in men with benign prostatic hyperplasia: A network meta-analysis. Cochrane Database Syst Rev. 2021 Jul 15;7(7):CD013656. doi: 10.1002/14651858.CD013656.pub2. PMID: 34693990; PMCID: PMC8543673.
3. Gratzke C, Barber N, Speakman MJ. Prostatic urethral lift vs transurethral resection of the prostate: 2-year results of the BPH6 prospective, multicentre, randomized study. BJU Int. 2017 May;119(5):767-775. doi: 10.1111/bju.13714. Epub 2016 Dec 21. PMID: 27862831
4. Hayes. Prostatic urethral lift (UroLift System) for treatment of symptoms associated with benign prostatic hyperplasia. Health Technology Assessment. Published June 9, 2020. Updated June 13, 2023. Accessed July 18, 2024. https://evidence.hayesinc.com/
5. Knight L, Dale M, Cleves A, et al. UroLift for treating lower urinary tract symptoms of benign prostatic hyperplasia: A NICE medical technology guidance update. Appl Health Econ Health Policy. 2022 Sep;20(5):669-680. doi: 10.1007/s40258-022-00735-y. Epub 2022 Jul 18. PMID: 35843995; PMCID: PMC9385790.
6. [1]Lerner LB, McVary KT, Barry MJ, et al. Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia: AUA guideline part I-initial work-up and medical management. J Urol. 2021 Oct;206(4):806-817. doi: 10.1097/JU.0000000000002183. Epub 2021 Aug 13. Erratum in: J Urol. 2021 Nov;206(5):1339. PMID: 34384237.

7. [2]Lerner LB, McVary KT, Barry MJ, et al. Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia: AUA guideline part II-surgical evaluation and treatment. J Urol. 2021 Oct;206(4):818-826. doi: 10.1097/JU.0000000000002184. Epub 2021 Aug 13. Erratum in: J Urol. 2022 Mar;207(3):743. Erratum in: J Urol. 2022 Oct;208(4):939. PMID: 34384236.
8. McVary, KT. Surgical treatment of benign prostatic hyperplasia (BPH). Updated June 26, 2024. Accessed July 18, 2024. www.uptodate.com.
9. Miller LE, Chughtai B, Dornbier RA, et al. Surgical reintervention rate after prostatic urethral lift: Systematic review and meta-analysis involving over 2,000 patients. J Urol. 2020 Nov;204(5):1019-1026. doi: 10.1097/JU.0000000000001132. Epub 2020 May 12. PMID: 32396049.
10. National Institute for Health and Care Excellence (NICE). UroLift for treating lower urinary tract symptoms of benign prostatic hyperplasia: Medical technologies guidance [MTG58]. Published May 4, 2021. Accessed July 22, 2024. https://www.nice.org.uk/guidance/mtg58.
11. Roehrborn CG, Barkin J, Gange SN, Shore ND. Five year results of the prospective randomized controlled prostatic urethral L.I.F.T. study. Can J Urol. 2017 Jun;24(3):8802-8813. PMID: 28646935.
12. Rukstalis D, Grier D, Stroup SP. Prostatic Urethral Lift (PUL) for obstructive median lobes: 12 month results of the MedLift study. Prostate Cancer Prostatic Dis. 2019 Sep;22(3):411-419. doi: 10.1038/s41391-018-0118-x. Epub 2018 Dec 12. PMID: 30542055; PMCID: PMC6760566.
13. Sandhu JS, Bixler BR, Dahm P. Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia (BPH): AUA Guideline Amendment 2023. J Urol. 2024 Jan;211(1):11-19. doi: 10.1097/JU.0000000000003698. Epub 2023 Sep 14. PMID: 37706750.
14. United States Food and Drug Administration (FDA). UroLift 2 System (UL2). Published July 31, 2020. Accessed July 17, 2024. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm.
15. United States Food and Drug Administration (FDA). UroLift 2 ATC Advanced Tissue Control System. Published September 23, 2023. Accessed July 17, 2024. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm
16. United States Food and Drug Administration (FDA). UroLift System (UL400). Published December 20, 2019. Accessed July 17, 2024. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm.
17. United States Food and Drug Administration (FDA). De novo classification request for Neotract's Urolift System. Published March 7, 2013. Accessed July 17, 2024. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm.
18. Xiang P, Wang M, Guan D, et al. A systematic review and meta-analysis of prostatic urethral lift for male lower urinary tract symptoms secondary to benign prostatic hyperplasia. Eur Urol Open Sci. 2020 Jun 4;19:3-15. doi: 10.1016/j.euros.2020.05.001. PMID: 34337448; PMCID: PMC8317884.