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

Last Approval: 8/10/2022
Next Review Due By: August 2023

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. 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. 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, 2021).

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. (e.g., 2016, 2017 and 2019). 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”.

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 (AMR, 2021):

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

The best available published evidence is the randomized sham-controlled FDA pivotal LIFT trial reported by Roehrborn et al. (2013) of a PUL device for treatment of lower urinary tract symptoms (LUTS) secondary to BPH. The patient and questionnaire administrator were blinded to the randomization. Men aged 50 years and older with an American Urological Association Symptom Index (AUASI) of >13, a maximum flow rate of 12 ml/second or less, and a prostate of 30 to 80 cc were randomized 2:1 to PUL or sham. The sham consisted of rigid cystoscopy with sounds mimicking those heard with the PUL placement. At three months, the AUASI reduction was assessed; the primary end point of the study was to have an AUASI reduction of 25% greater than the sham. The PUL subjects were also assessed at one year for LUTS, peak urinary flow rate, quality of life and sexual function. Altogether, 206 men were randomized (140 to PUL, 66 to sham). Patients were evaluated at 1, 3, 6, and 12 months. The PUL patients had an AUASI reduction of 11.1 + 7.67 whereas the sham patients change was 5.9 + 7.66 (P = 0.003) at three months. The PUL reduction remained at 12 months. Peak urinary flow was increased 4.4 ml at 3 months and remained at 4.0 ml/second at 12 months (p <0.001). There was no new ejaculatory or erectile dysfunction. Adverse events were described as mild and transient. There was a 5% retreatment rate at one year.

A follow up to this study by Roehrborn et al. (2015) reported that at 2 years, 106 men treated with the UroLift were evaluable for the per-protocol analysis. In these patients, the AUASI score (−9.2 ± 7.57), QOL (−2.2 ± 1.71), and Qmax (mean 4.2 mL per second) remained improved by 42%, 48%, and 58%, respectively (P<0.0001 for all). The reduction in the BPHII score was also sustained compared with baseline (−55.6 ± 3.4) (P<0.0001). Three-year results of the same LIFT trial of the PUL in 206 men with bothersome LUTS due to BPH reported PUL offers rapid improvement in voiding and storage symptoms, quality of life and flow rate that is durable to 3 years. In addition, it preserved total sexual function while offering a rapid return to normal physical activities.

As a follow-up to the LIFT trial, Roehrborn et al. (2017) reported the five-year results of a prospective, multi-center, randomized, blinded sham control trial of the PUL in men with bothersome lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH). At 19 centers in North America and Australia, 206 subjects ≥ 50 years old with International Prostate Symptom Score (IPSS) > 12, peak flow rate (Qmax) ≤ 12 mL/s, and prostate volume 30 cc-80 cc were randomized 2:1 to the PUL procedure or blinded sham control. In PUL permanent UroLift implants are placed to hold open the lateral lobes of the prostate to reduce urinary obstruction. After randomized comparison at 3 months and the only opportunity to add more PUL implants, PUL patients were followed to 5 years. LUTS severity (IPSS), quality of life (QOL), BPH Impact Index (BPHII), Qmax, sexual function, and adverse events were assessed throughout follow up. IPSS improvement after PUL was 88% greater than that of sham at 3 months. LUTS and QOL were significantly improved by 2 weeks with return to preoperative physical activity within 8.6 days. Improvement in IPSS,

QOL, BPHII, and Qmax were durable through 5 years with improvements of 36%, 50%, 52%, and 44% respectively. No difference was seen between Intent to Treat and Per Protocol populations. Surgical retreatment was 13.6% over 5 years. Adverse events were mild to moderate and transient. Sexual function was stable over 5 years with no de novo, sustained erectile or ejaculatory dysfunction.

McVary et al. (2014) analyzed the sexual function of the men in the Roehrborn et al. studies. Men 50 years or older with prostates 30-80 cc, or an International Prostate Symptom Score (IPSS) of >12, and peak urinary flow rate (Qmax) of ≤12 ml/s were randomized 2:1 between PUL and sham. Blinded groups were compared at three months and active arm then followed to 12 months for LUTS with IPSS and for sexual function with sexual health inventory for men (SHIM) and Male Sexual Health Questionnaire for Ejaculatory Dysfunction (MSHQ-EjD). No evidence of degradation in erectile or ejaculatory function after PUL was found. SHIM and MSHQ-EjD scores were not different from control at 3 months but were modestly improved and statistically different from baseline at 1 year.

McNicholas et al. (2013) described the outcomes of 102 men with symptomatic BPH treated at seven centers in five countries. The study was had a single arm and was not blinded. Average age was 68 years, average prostate size was 48 cm3, and average International Prostate Symptom Score (IPPS) was 23. Patients were followed at 2 and 6 weeks, and 3, 6, and 12 months postoperatively. The mean IPPS improved 36%, the mean QOL improved 39%, and the maximum flow rate (Qmax) improved by 38% by two weeks. At 12 months observation, these rates of improvement were 52%, 53% and 51% respectively. These results were statistically significant although the postvoid residual volume (PVR) did not show a statistically significant change. There were no reports of retrograde ejaculation. Transurethral resection of the prostate (TURP) occurred in four patients (6.5%). Adverse events were short duration of dysuria (25%), hematuria (16%), and urgency (10%).

Cantwell et al. (2014) conducted a prospective crossover trial of PUL in patients with LUTS due to BPH. Men 50 years and older with an IPPS > 13, a Qmax of <12 mL/s, and a prostate of 30-80 mL were enrolled. The study was prospective, randomized, controlled, blinded, and conducted in 19 centers in the USA, Canada, and Australia. Patients underwent a sham procedure with rigid cystoscopy, inability to see the operator or endoscopy imaging, and hearing sounds associated with an operative procedure. Three to six months later the patients were re-assessed and a PUL was placed. At entry, there were 66 men; 53 (80%) elected to have the PUL. There was a similar change in the IPPS for both sham and crossover PUL patients at two weeks, but the change continued to increase in the latter group and reached statistical significance at three months. In contrast, the urinary flow rate change was more durable three months after the sham rigid cystoscopy showing a 2.4 mL/s increase in Qmax at 3 months. There was further improvement at 3 months post-PUL which was maintained at 12 months. Improvements in IPPS 3 months post-PUL was 11.1 points or 122% greater than the three-month post-sham improvement of 5.0 points ($P < 0.001$). Improvements were similar to those noted in the study by Roehrborn, et al. described above. Clinically and statistically significant improvement in Health Related Quality of Life (HRQL) scores and BPHII post-PUL also occurred. Sexual function was maintained. Adverse events were primarily mild except for two patients who developed urinary retention. One patient progressed to TURP.

Chin et al. (2012) evaluated a PUL device placed in 64 men, > 55 years old, with moderate to severe symptomatic benign prostatic hyperplasia treated in six (6) Australian facilities. Effectiveness was evaluated at 2 weeks and 3, 6, 12, and 24 months. The IPPS decreased 42% in 2 weeks, 49% at 6 months, and 42% at two years. Patients treated early in the study had a 34% decrease at three years. The quality-of-life score (QOL) score improved from an average of 4.9 at baseline to 2.7 at 2 weeks, and 2.5 at one and two years. The BPH Impact Index (BPHII) decreased 39% at 2 weeks with a 60% reduction at 2 years; these results were statistically significant at each measurement period. Peak flow increased an average amount of > 30% at all intervals. There were no findings of degraded erectile function. Numbers of evaluable patients were not clear although it was noted that the sample size was reduced at 24 months because not all of the patients had reached that point of follow-up. There was no active or sham control group. Twenty percent (20%) (13/64) of the initially treated patients required repeat treatment.

National and Specialty Organizations

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] Learner 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.

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT 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 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

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 was also reviewed by IRO.
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.

REFERENCES

Government Agencies

1. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database (no National Coverage Determination identified). Available from CMS. Accessed July 7, 2022.
2. United States Food and Drug Administration (FDA). De novo classification request for Neotract's Urolift System. Available from FDA. Published March 7, 2013. Accessed July 7, 2022.
3. United States Food and Drug Administration (FDA). UroLift System (UL400). Available from FDA. Published December 20, 2019. Accessed July 7, 2022.

Evidence Based Reviews and Publications

1. Advanced Medical Reviews (AMR) Peer Review. Policy reviewed in June 2021 by an AMR practicing, board-certified physician in the area of Urology.
2. Hayes. Health technology assessment: Prostatic urethral lift (UroLift System) for treatment of symptoms associated with benign prostatic hyperplasia. Available from Hayes. Published June 9, 2020. Updated July 9, 2021. Accessed July 7, 2022. Registration and login required.

Peer Reviewed Publications

1. Cantwell AL, Bogache WK, Richardson SF, Tutrone RF, Barkin J, Fagelson JE, et al. Multicentre prospective crossover study of the 'prostatic urethral lift' for the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia. BJU Int. 2014 Apr;113(4):615-22. doi: 10.1111/bju.12540. Accessed July 7, 2022.
2. Chin PT, Bolton DM, Jack G, Rashid P et al. Prostatic urethral lift: two-year results after treatment for lower urinary tract symptoms secondary to benign prostatic hyperplasia. Urology. 2012 Jan;79(1):5-11. doi: 10.1016/j.urology.2011.10.021. Accessed July 7, 2022.
3. Loloi J, Feiertag N, Gautam K, Maria P. An update on the outcomes of patients treated with urolift for benign prostatic hyperplasia. Res Rep Urol. 2021;13:347-355. Accessed July 7, 2022.
4. McNicholas T. The UroLift system: A progress report. Trends in urology & men's health. 2020;11(2):13-17. doi:10.1002/tre.739.
5. McNicholas TA, Woo HH, Chin PT, et al. Minimally invasive prostatic urethral lift: surgical technique and multinational experience. Eur Urol. 2013 Aug;64(2):292-9. doi: 10.1016/j.eururo.2013.01.008. Accessed July 7, 2022.
6. McVary KT, Gange SN, Shore ND et al. Treatment of LUTS secondary to BPH while preserving sexual function: Randomized controlled study of prostatic urethral lift. J Sex Med. 2014 Jan;11(1):279-87. doi: 10.1111/jsm.12333. Accessed July 7, 2022.
7. Parsons JK, Dahm P, Köhler TS, et al. Surgical management of lower urinary tract symptoms attributed to benign prostatic hyperplasia: AUA Guideline amendment 2020. J Urol 2020; 204: 799. Accessed July 7, 2022.
8. Roehrborn CG, Barkin J, Gange SN, et al. Five-year results of the prospective randomized controlled prostatic urethral L.I.F.T. study. Can J Urol. 2017 Jun;24(3):8802-8813. Available here. Accessed July 7, 2022.
9. Roerborn CG, Rukstalis DB, Barkin J, et al. Three-year results of the prostatic urethral L.I.F.T. study. Can J Urol. 2015 Jun;22(3):7772-82. Available here. Accessed July 7, 2022.
10. Roehrborn CG, Gange SN, Shore ND, et al. The prostatic urethral lift for the treatment of lower urinary tract symptoms associated with prostate enlargement due to benign prostatic hyperplasia: The L.I.F.T. Study. J Urol. 2013 Dec;190(6):2161-7. doi: 10.1016/j.juro.2013.05.116. Accessed July 7, 2022.
11. Rukstalis D, Grier D, Stroup SP, et al. Prostatic Urethral Lift (PUL) for obstructive median lobes: 12 month results of the MedLift Study. Prostate cancer and prostatic diseases. 2019;22(3):411-419. doi:10.1038/s41391-018-0118-x. Accessed July 7, 2022.

National and Specialty Organizations

1. [1] Lerner LB, McVary, KT, Barry MJ, et al. Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia: American Urological Association (AUA) guideline part I, initial work-up and medical management. J Urol. 2021 Oct;206(4):806-817. doi: 10.1097/JU.0000000000002183. Accessed July 7, 2022.
2. [2] Lerner LB, McVary, KT, Barry MJ, et al. Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia: American Urological Association (AUA) guideline part II, surgical evaluation and treatment. J Urol. 2021 Oct;206(4):818-826. doi: 10.1097/JU.0000000000002184. Accessed July 7, 2022.
3. National Institute for Health and Care Excellence (NICE). UroLift for treating lower urinary tract symptoms of benign prostatic hyperplasia: Medical technologies guidance [MTG58]. Available from NICE. Published May 4, 2021. Accessed July 7, 2022.

Other Peer Reviewed and National Organization Publications (used in the development of this policy)

1. Eure G, Gange S, Walter P, et al. Real-world evidence of prostatic urethral lift confirms pivotal clinical study results: 2-year outcomes of a retrospective multicenter study. J Endourol. 2019 Jul;33(7):576-584. doi: 10.1089/end.2019.0167. Accessed July 7, 2022.
2. Gratzke C, Barber N, Speakman MJ, et al. 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. Accessed July 7, 2022.
3. Jung JH, Reddy B, McCutcheon KA, et al. Prostatic urethral lift for the treatment of lower urinary tract symptoms in men with benign prostatic hyperplasia. Cochrane Database Syst Rev. 2019;5:CD012832. Available here. Accessed July 7, 2022.
4. Kim JH, Lee KS, Kim TH. Evaluation of clinical outcomes of prostatic urethral lift for benign prostatic hyperplasia: an Asian population study. World J Mens Health. 2020 Jul;38(3):338-344. doi: 10.5534/wjmh.190015. Accessed July 7, 2022.
5. Miller LE, Chughtai B, Dornbier RA, McVary KT. 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. Accessed July 7, 2022.
6. Mortfeldt, A. Efficacy of prostatic urethral lift in comparison to transurethral resection of prostate. JAAPA. 2020 Nov;33(11):10-13. doi: 10.1097/01.JAA.0000718264.76485.bc. Accessed July 7, 2022.
7. Roehrborn CG, Gange SN, Shore ND, et al. Durability of the prostatic urethral lift: 2-year results of the L.I.F.T. study. Urol Pract. 2015;2:26-32. Accessed July 7, 2022.
8. Rukstalis D, Grier D, Stroup SP, et al. 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. Accessed July 7, 2022.
9. Rukstalis D, Rashid P, Bogache WK, et al. 24-month durability after crossover to the prostatic urethral lift from randomised, blinded sham. BJU Int. 2016 Oct;118 Suppl 3:14-22. doi: 10.1111/bju.13666. Accessed July 7, 2022.
10. Sievert KD, Schonthaler M, Berges R, et al. Minimally invasive prostatic urethral lift (PUL) efficacious in TURP candidates: a multicenter German evaluation after 2 yearsWorld J Urol. 2019 Jul;37(7):1353-1360. doi: 10.1007/s00345-018-2494-1. Accessed July 7, 2022.
11. Sonksen J, Barber NJ, Speakman MJ, et al. Prospective, randomized, multinational study of prostatic urethral lift versus transurethral resection of the prostate: 12-month results from the BPH6 study. Eur Urol. 2015 Oct;68(4):643-52. doi: 10.1016/j.eururo.2015.04.024. Accessed July 7, 2022.
12. Srinivasan A, Wang R. An update on minimally invasive surgery for benign prostatic hyperplasia: techniques, risks, and efficacy. World J Mens Health. 2020 Oct;38(4):402-411. doi: 10.5534/wjmh.190076. Accessed July 7, 2022.
13. Tanneru K, Gautam S, Norez D, et al. Meta-analysis and systematic review of intermediate-term follow-up of prostatic urethral lift for benign prostatic hyperplasia. Int Urol Nephrol. 2020 Jun;52(6):999-1008. doi: 10.1007/s11255-020-02408-y. Accessed July 7, 2022.

APPENDIX

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