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

Last Approval: 08/12/2026
Next Review Due By: August 2027

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

Benign prostatic hyperplasia (BPH) is a common, age-related condition characterized by an overgrowth of both stromal and epithelial cells within the transition zone of the prostate, leading to the formation of distinct nodules. This cellular proliferation differs from benign prostatic hypertrophy, which refers to an overall enlargement of prostate cells without the development of nodules. Together, these processes may result in benign prostatic enlargement, which can cause benign bladder outlet obstruction. The prevalence of BPH increases significantly with age, affecting approximately 70% of men in their 60s and up to 80% of men aged 70 and older in the United States. BPH is closely linked with lower urinary tract symptoms (LUTS), a group of urinary issues classified into storage (e.g., urgency, frequency, nocturia), voiding (e.g., hesitancy, weak stream, straining), and post-void (e.g., dribbling, incomplete emptying) symptoms. LUTS prevalence also rises with age, becoming increasingly common in men over 80. Management of LUTS attributed to BPH spans behavioral strategies, pharmacologic therapy, and procedural and surgical interventions, selected according to symptom severity and patient preference (McVary 2024).

The **prostatic urethral lift (PUL)** or UroLift System is a minimally invasive treatment designed to alleviate lower urinary tract symptoms associated with BPH. The procedure involves the transurethral placement of small, permanent implants that retract obstructive prostate tissue, thereby widening the urethral lumen and improving urine flow while preserving the prostate gland (Hayes 2023; McVary 2024). Typically performed in an outpatient setting under cystoscopic guidance, the procedure involves the delivery of approximately four to six implants into the prostatic urethra to maintain urethral patency. A final cystoscopy is performed to confirm proper placement of the implants. The most commonly reported adverse events include hematuria, dysuria, micturition urgency, pelvic discomfort, and urge incontinence (Hayes 2023). PUL is intended to provide symptom relief while avoiding the higher morbidity associated with more invasive surgical options.

Regulatory Status

The UroLift System received initial marketing authorization from the U.S. Food and Drug Administration (FDA) on September 13, 2013, through the de novo classification process as a Class II medical device under product code PEW. It was approved for use as a permanent implant to relieve LUTS caused by BPH in men aged 50 years and older.

Subsequent clearances of the UroLift System have been granted based on substantial equivalence to the original device. In 2019, the FDA expanded the indications to include the treatment of urinary outflow obstruction due to both lateral and median lobe hyperplasia in men aged 45 years and older. The FDA also revised the contraindication related to prostate volume, changing the upper limit from greater than 80 cc to greater than 100 cc. The UroLift 2 System (K201837) and UroLift 2 ATC (K232558) received FDA clearance on July 31, 2020, and September 22, 2023, respectively, for the same indications and contraindications as those outlined in the 2019 clearance.

According to the FDA, the UroLift 2 System and UroLift 2 ATC System should not be used in patients with a prostate volume greater than 100cc, active urinary tract infections, urethral conditions that would prevent safe insertion of the delivery system into the bladder, urinary incontinence due to an incompetent sphincter, or current gross hematuria.

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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 as an 8 or above on the International Prostate Symptom Score by the American Urological Association (AUA)
3. Signs of urinary outflow 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 ml/sec on a voided volume that is greater than 125ml)
4. Refractory to or intolerant of standard BPH medication (e.g., alpha-blockers, 5-alpha reductase inhibitors, PDE5 inhibitors)
5. Presence of lateral and/or median lobe hyperplasia
6. Prostatic volume less than or equal to 100ml
7. No active urinary tract infection
8. No urinary incontinence due to incompetent sphincter

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

Randomized Controlled Trials

Gratzke et al. (2017) reported on the BPH6 study, a randomized controlled trial that compared prostatic urethral lift (PUL) with transurethral resection of the prostate (TURP) in 80 men with symptomatic benign prostatic hyperplasia (BPH). Participants were randomized to either PUL (n=45) or TURP (n=35). Over a two-year follow-up, both groups experienced meaningful improvements in International Prostate Symptom Score (IPSS), quality of life (QOL), peak urinary flow rate (Qmax), and the BPH Impact Index (BPHII). However, PUL was found to be non-inferior to TUPR for the primary composite endpoint (P = 0.0002) and demonstrated superiority in terms of overall patient centered outcomes (P = 0.006). These findings supported PUL as a less invasive alternative with comparable symptom relief.

Roehrborn et al. (2017) conducted the L.I.F.T study, a multicenter, randomized controlled, and blinded clinical trial evaluating the efficacy of PUL in men with lateral lobe (LL) obstruction due to benign prostatic hyperplasia (BPH). A total of 206 men were randomized to undergo either PUL (n=140) or sham procedure with rigid cystoscopy procedure (n=66). Both patients and assessors were blinded to the treatment group for the initial three months, after which unblinding occurred. Patients in the PUL group were followed for five years. Key outcomes included the IPSS, QOL, Qmax, and the BPHII. The study demonstrated that PUL produced durable symptom relief over five years, with sustained improvements in the key indicators of 36% in IPSS, 50% in QOL, 52% in BPHII, and a 44% increase in Qmax. The procedure had a low surgical retreatment rate of 2-3% per year and avoided many of the complications associated with more invasive surgical approaches.

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Systematic Reviews and Meta-Analyses

Warli et al. (2024) performed a systematic review and meta-analysis to evaluate the efficacy and safety of PUL as a minimally invasive treatment for lower urinary tract symptoms (LUTS) due to BPH while preserving sexual function. The review included seven randomized controlled trials with a combined 378 participants. Using a random-effects model, the authors found that PUL produced a statistically significant improvement in International Prostate Score (IPSS) compared with sham, with a mean difference (MD) of 5.51 points ($p< 0.0001$). The analysis also demonstrates significant improvements in Qmax, quality-of-life scores, and BPHII, though the authors noted variability in how the secondary outcomes were reported across trials. Importantly, sexual function was preserved, and adverse event rates did not differ significantly between PUL and sham groups. Limitations included the modest number of eligible RCTs, short term follow-up (≤ 3 months), and heterogeneity in outcome reporting. Overall, the authors concluded that PUL is an effective and minimally invasive option for appropriately selected men with LUTS due to BPH.

Franco et al. (2021) conducted a network meta-analysis to evaluate the effectiveness and safety of minimally invasive treatments for lower urinary tract symptoms (LUTS) in men with BPH. The meta-analysis included 27 RCTs involving 3,017 men with severe LUTS and compared various procedures including PUL, prostatic arterial embolization, convective radiofrequency water vapor therapy, and transurethral microwave thermotherapy. Primary outcomes assessed were urinary symptoms, QOL, and adverse effects. Findings specific to PUL showed it produced little to no difference in urinary symptoms or QOL compared to TURP but was associated with a lower risk of major adverse events. PUL also had favorable rankings in terms of symptoms scores and retreatment rates. However, the effect of PUL on sexual function, particularly erectile and ejaculatory outcomes, remained uncertain.

Miller et al. (2020) completed a systematic review and meta-analysis to evaluate the surgical reintervention rate following PUL. The analysis included 11 studies comprising 2,016 patients, all with a minimum of one year of follow-up. A total of 153 surgical reinterventions were reported with the most common being TURP (51%), repeat PUL (32.7%), and device explant (19.6%). The mean surgical reintervention rate across all studies was 6% per year. Reintervention rates varied by follow-up duration, with studies averaging one year showing a rate of 4.3%, those with 1-3 years showing 10.7%, and studies exceeding three years reporting a rate of 5.8% per year.

Xiang et al. (2020) performed a systematic review and meta-analysis of 19 studies involving 650 patients who underwent PUL. The review evaluated changes in IPSS, BPHII, QOL, Qmax, and post-void residual volume (PVR) overtime. The pooled results demonstrated a consistent reduction in IPSS ranging from -10.97 at 1–1.5 months to -9.73 at 24 months, along with corresponding improvements in BPHII and QOL scores. Qmax increased by an average of 3.44 to 4.26 mL/s, and PVR showed mild improvement over time. The most common complications—such as dysuria, hematuria, pelvic pain, urinary tract infection, and incontinence—were typically mild and self-limited. The study concluded that PUL effectively relieves prostatic symptoms for up to two years, with a favorable safety profile and preservation of sexual function. Approximately 3.6% to 18.8% of patients required TURP within 24 months.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Rukstalis et al. (2019) conducted the MedLift study, a single-arm clinical trial evaluating the safety and effectiveness of PUL in patients with obstructive median lobe enlargement who also met the L.I.F.T study criteria for lateral lobe obstruction. The study included 45 men and used the sham arm of the L.I.F.T trial as a historical control group. Participants were followed for 12 months post-procedure. Findings showed that the clinical benefits of PUL in patients with obstructive median lobe were similar to those seen in lateral lobe patients, with significant and sustained improvements in IPSS, QOL, Qmax, and BPHII. The study supported expanding the indication of PUL to appropriately selected patients with median lobe involvement.

National and Specialty Organizations

The **American Urological Association (AUA)** published the guideline *Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia: AUA Guideline (2026) Part III: Procedural/Surgical Management* (Goueli et al. 2026) which provides an updated, evidence-based framework for evaluation and treatment. The guideline emphasizes that LUTS is the primary driver of treatment decisions that shared decision- making should occur at every stage of management, incorporating patient priorities such as ejaculatory preservation, retreatment tolerance, anesthesia considerations, and catheter tolerance. Recommended initial evaluation includes medical history, physical examination, standardized symptom scoring, and urinalysis, PSA testing, post void residual measurement, uroflowmetry, and urodynamics when clinically indicated. The guideline outlines a tiered approach to therapy, beginning with behavioral and lifestyle interventions, followed by evidence-based pharmacologic options including

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alpha-blockers, 5-alpha reductase inhibitors, phosphodiesterase-5 inhibitors, and combination regimes. Patients do not respond to or decline medical therapy, or who present with specific complications, should be considered for procedural intervention. The 2026 guidelines identify renal insufficiency secondary to BPH as an indication for procedural therapy and directs clinicians to offer procedural therapies to patients with renal insufficiency, refractory urinary retention, recurrent urinary tract infections, recurrent bladder stones, gross hematuria due to BPH, or LUTS/BPH refractory to or incompatible with other therapies. Procedural therapy selection is individualized based on the prostate size, morphology, patient goals, and technology availability. The guideline provides specific prostate volume creatures each modality. Overall, the 2026 AUA guidelines support a patient-centered, anatomy guided approach to LUTS/BPH management, with procedural therapy including PUL appropriate for patients with renal insufficiency due to BPH and selected for shared decision making.

The **National Institute for Health and Clinical Excellence (NICE)** (2021) published *Medical technologies guidance [MTG58]* supporting the use of the UroLift System as a minimally invasive alternative to transurethral resection of the prostate (TURP) and holmium laser enucleation of the prostate (HoLEP). NICE recommends the procedure in appropriate patients and considers it suitable for outpatient or same-day settings due to its less invasive nature and quicker recovery time.

NICE reaffirmed its recommendation for UroLift, citing a growing body of supporting clinical evidence. Although UroLift may not achieve the same degrees of symptom relief as TURP, it is viewed as a favourable option for appropriately selected patients due to its lower complication profile. Specifically, NICE continues to recommend UroLift in appropriate patients, particularly those seeking a less invasive alternative with reduced risks (Knight et al. 2022).

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

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)

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

08/12/2026	Policy revised. Rephrased IPSS score from ‘ score above 7 ‘ to ‘as an 8 or above’ for clarity – no practice change. Added criteria of ‘No urinary incontinence due to incompetent sphincter’. Removed criteria of ‘Normal renal function’. IRO Peer Review on July 7, 2026, by a practicing physician board certified in Urology.
08/13/2025	Policy reviewed, no changes to coverage criteria.
08/14/2024	Policy revised. Coverage criteria changed based on FDA indications for use to include patients with median lobe hyperplasia. Removed nickel allergy. 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. Removed Supplemental Information section.
08/10/2022	Policy reviewed, no changes to coverage criteria.
08/11/2021	Policy revised; 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 Urology.
09/16/2020	Policy reviewed, no changes, updated references, added TOC.
09/18/2019	Policy reviewed, no changes, updated references**.**
03/08/2018	Policy revised and updated from investigational status to medically necessary based on newly published evidence. Summary of

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	Medical Evidence (and references) updated with professional guidelines.
06/22/2017	Policy reviewed, no changes.
12/14/2016	Policy reviewed, no changes.
12/16/2015	Policy reviewed, no changes.
06/02/2015	New policy.

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