Mass General Brigham
Health Plan

Medical Policy
Prostatic Urethral Lift

Policy Number: 045

	Commercial and Qualified Health Plans	Mass General Brigham ACO	Medicare Advantage	OneCare	Senior Care Options (SCO)
Authorization required					
No Prior Authorization	X	X	X	X	X

Overview
The purpose of this document is to describe the guidelines Mass General Brigham Health Plan uses to determine medical necessity for prostatic urethral lift (Urolift®).

Coverage Guidelines
Mass General Brigham Health Plan covers prostatic urethral lift in members with moderate-to-severe lower urinary tract obstruction (defined by American Urological Association [AUA] symptom score >7) due to benign prostatic hyperplasia (BPH) when ALL the following are met:

- The member has a diagnosis of BPH, and symptoms are caused by enlargement of the median and/or lateral prostate lobes; and
- The member has persistent or progressive lower urinary tract symptoms despite medical therapy (alpha1-adrenergic antagonists for at least 3 months, or 5 alpha-reductase inhibitors for at least 6 months, or combination medication therapy maximally titrated), OR is unable to tolerate medical therapy; and
- Prostate gland volume is ≤100 cc; and
- Prostate anatomy demonstrates bladder neck without evidence of a stricture.

Exclusions
Mass General Brigham Health Plan does not provide coverage for prostatic urethral lift in the following instances:

- The member has a contact dermatitis nickel allergy; or
- The member has prostate-specific antigen level ≥3 ng/mL and has not had appropriate testing to exclude diagnosis of prostate cancer; or
- The member has had a recent urinary tract infection or prostatitis; or
- The member has a urethral condition that may prevent insertion of delivery system into the bladder.

Medicare Variation
Mass General Brigham Health Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) for medical necessity determinations for its Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs), and documentation included in the Medicare manuals are the basis for medical necessity determinations. When

there is no guidance from CMS for the requested service, Mass General Brigham Health Plan's medical policies are used for medical necessity determinations. **At the time of Mass General Brigham Health Plan's most recent policy review, Medicare had no NCDs or LCDs for prostatic urethral lift.**

MassHealth Variation
Mass General Brigham Health Plan uses guidance from MassHealth for medical necessity determinations for its Mass General Brigham ACO members. When there is no guidance from MassHealth for the requested service, Mass General Brigham Health Plan's medical policies are used for medical necessity determinations. **At the time of Mass General Brigham Health Plan's most recent policy review, MassHealth had no medical necessity criteria for prostatic urethral lift.**

OneCare and SCO Variation
Mass General Brigham Health Plan uses guidance from CMS for medical necessity determinations for its OneCare and SCO plan members. NCDs, LCDs, LCAs, and documentation included in the Medicare manuals are the basis for medical necessity determinations. When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan uses medical necessity guidelines from MassHealth. When there is no guidance from CMS or from MassHealth, Mass General Brigham Health Plan's medical policies are used for medical necessity determinations.

Definitions
Prostatic Urethral Lift (PUL): The prostatic urethral lift (Urolift®) mechanically opens the prostatic urethra with implants that are placed transurethrally under cystoscopic visualization, thereby separating the encroaching prostatic lobes. The PUL is introduced into the urethra and used to compress the prostate tissue, thereby increasing the urethral lumen and reducing obstruction to urine flow. It is a minimally invasive, short endoscopic procedure that can be done under local, general, or regional anesthesia.

Benign Prostatic Hyperplasia (BPH): Benign prostatic hyperplasia (BPH) is a common disorder among older individuals 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 individuals ages 70 to 79.

Codes

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage.

Authorized CPT/HCPCS 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) Maximum 6 units
C9739	Cystourethroscopy, with insertion of transprostatic implant; one to three implants
C9740	Cystourethroscopy, with insertion of transprostatic implant; four or more implants

Summary of Evidence

The Prostatic Urethral Lift (PUL) procedure has been studied across numerous clinical trials and real-world settings, involving thousands of patients. These studies, including large randomized controlled trials and long-term follow-up investigations, have demonstrated its efficacy and safety in treating symptoms of benign prostatic hyperplasia (BPH). The L.I.F.T. study (Roehrborn et al., 2013 and 2017), a multicenter, randomized, sham-controlled, blinded trial, demonstrated significant improvements in lower urinary tract symptoms (LUTS), urinary flow, and quality of life over 12 months that were sustained to 5 years, with no incident erectile or ejaculatory dysfunction, establishing the foundation for PUL's clinical use. In this study, lateral lobe obstruction only was treated, and men with median lobe obstruction were excluded. The single-arm MedLift study (Rukstalis et al., 2019) expanded on this by focusing on patients with obstructive median lobes (OML), a group excluded from earlier research, and found comparable improvements in urinary symptoms, quality of life, and urinary flow to those without OML. The BPH6 study (Sonksen et al., 2015) randomized patients to PUL or transurethral resection of the prostate (TURP), and demonstrated that PUL offered faster recovery, superior preservation of sexual function, and fewer adverse effects, though TURP achieved slightly greater symptom relief at 12 months. Real-world evidence, such as the Retrospective Multicenter Study by Eure et al., 2019 confirmed the durability of PUL's benefits over two years in patients with OML, aligning with findings from controlled trials. Meta-analyses (e.g., Jing et al., 2020; Xiang et al., 2020) further validated these results by synthesizing data across multiple studies, demonstrating significant and sustained improvements in LUTS, quality of life, and Qmax up to 24 months.

While PUL generally demonstrates durable symptom relief, a small percentage of patients may require retreatment due to recurrent symptoms or incomplete initial response. Some patients may experience persistent mild to moderate urinary symptoms despite successful PUL procedures. The success of PUL may vary depending on factors such as prostate size, the presence of specific anatomical variations, and individual patient characteristics. Ongoing research focuses on refining PUL techniques, including advancements in implant design and delivery systems, to potentially improve outcomes and expand the applicability of the procedure. Continued long-term follow-up studies are investigating the long-term durability of PUL's benefits and identifying potential predictors of long-term success. While TURP remains the gold standard for treatment of BPH, PUL provides a minimally invasive alternative with rapid recovery, fewer complications, and a strong preservation of sexual health, making it particularly appealing to patients prioritizing these outcomes. The robust evidence base-spanning randomized trials, real-world studies, and meta-analyses-supports PUL as an effective and well-tolerated option for managing benign prostatic hyperplasia (BPH). Based on the studies cited above and consistent with practice guidelines from the AUA (Sandhu et al. 2023), MGB Health Plan considers PUL to be medically necessary and well-supported by high-quality evidence for individuals with obstructive symptoms, with prostate volumes of 30-80mL, and without an obstructive median lobe. Although the quality of evidence is lower for individuals with larger prostates and with obstructive median lobes, MGB Health plan considers the evidence adequate to support medical necessity for individuals with obstructive symptoms, prostate volumes up to 100mL, and with an obstructive median lobe.

Effective
January 2026: Ad hoc update. Updated prior authorization table and added variation for OneCare and SCO members. Fixed code disclaimer.
March 2025: Annual update. Summary of evidence added. References updated.
December 2024: Ad hoc update. Taken off prior authorization. MassHealth variation language added. Clarified Medicare variation. Fixed typo in medical necessity criteria.
March 2024: Annual update. References updated.
March 2023: Annual update. Medicare Advantage added to table. Medicare variation language added. References updated.

March 2022: Annual update. Under Coverage Guidelines; changed prostate gland volume from ≤80 to ≤100. Exclusions were updated to remove member does not have prostate-specific antigen level ≥3 ng/mL. Added exclusion that member has had appropriate testing to exclude diagnosis of prostate cancer. References updated.
March 2021: Annual update. References updated.
December 2020: Ad hoc update. Code update.
April 2020: Annual update. References updated.
April 2019: Annual update. Under Coverage Guidelines, revised medical therapy to clarify requirement; 3 months for alpha1-adrenergic antagonists or 5 alpha-reductase inhibitors for at least 6 months. Removed guideline that member is a poor candidate for other surgical procedures for BPH using general anesthesia. Revised exclusion regarding urinary tract infection/prostatitis removing the one-year requirement.
September 2018: Effective date.

References

Cunningham G., Kadmon, D, et al. Transurethral procedures for treating benign prostatic hyperplasia. UpToDate. June 2018

Eastham JA, Auffenberg GB, Barocas DA, et al.: Clinically localized prostate cancer: AUA/ASTRO guideline part I: introduction, risk assessment, staging and risk-based management. J Urol 2022; https://doi.org/10.1097/JU.0000000000002757.

Eastham JA, Auffenberg GB, Barocas DA, et al.: Clinically localized prostate cancer: AUA/ASTRO guideline part II: principles of active surveillance, principles of surgery and follow-up. J Urol 2022; https://doi.org/10.1097/JU.0000000000002758.

Eastham JA, Auffenberg GB, Barocas DA, et al.: Clinically localized prostate cancer: AUA/ASTRO guideline part III: principles of radiation and future directions. J Urol 2022; https://doi.org/10.1097/JU.0000000000002759

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. PMID: 31115257.

Eure G, Rukstalis D, Roehrborn C. Prostatic Urethral Lift for Obstructive Median Lobes: Consistent Results Across Controlled Trial and Real-World Settings. J Endourol. 2023 Jan;37(1):50-59. doi: 10.1089/end.2022.0324. Epub 2022 Sep 9. PMID: 35876440; PMCID: PMC9810349.

Food and Drug Administration (FDA). UroLift System (UL400). https://www.accessdata.fda.gov/cdrh_docs/pdf19/K193269.pdf. Published December 20, 2019. Accessed February 25 2022.

Hayes, Inc. Health Technology Assessment. Prostatic urethral lift (UroLift System) for treatment of symptoms associated with benign prostatic hyperplasia. Lansdale, PA: Hayes Inc.; June 2020; amended August 2021. Updated July 2022.

Jing J, Wu Y, Du M, et al. Urethral Lift as a Safe and Effective Procedure for Prostatic Hyperplasia Population: A Systematic Review and Meta-Analysis. Front Surg. 2020 Dec 8;7:598728. doi: 10.3389/fsurg.2020.598728. PMID: 33425981; PMCID: PMC7793831.

Jung JJ, Reddy BB, McCutcheon KK. Prostatic urethral lift for the treatment of lower urinary tract symptoms in men with benign prostatic hyperplasia. Cochrane Database Syst Rev, 2019 May 28;5:CD012832. PMID 31128077

McNicholas TA, Woo HH, Chin PT, et al. Minimally invasive prostatic urethral lift: surgical technique and multinational experience. *Eur Urol.* Aug 2013;64(2):292-299. PMID 23357348

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*. Dec 2013;190(6):2161-2167. PMID 23764081

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.* Jun 2017;24(3):8802-8813. PMID 28646935

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. Epub 2018 Dec 12. PMID: 30542055; PMCID: PMC6760566.

Sandhu JS, Bixler BR, Dahm P, et al., Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia (BPH): AUA Guideline Amendment 2023. *J Urol.* 2023;10.1097/JU.0000000000003698. https://doi.org/10.1097/JU.0000000000003698.

Sarma AV, Wei JT. Clinical practice. Benign prostatic hyperplasia and lower urinary tract symptoms. *N Engl J Med*. Jul 19 2012;367(3):248-257. PMID 22808960

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.* Oct 2015;68(4):643-652. PMID 25937539

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. *International Urology and Nephrology* 2020; Feb 17. doi: 10.1007/s11255-020-02408-y

U.S. Food and Drug Administration. Center for devices and radiological health (CDRH). Rockville (MD): U.S. Department of Health and Human Services. 510k Premarket notification: UroLift system. K130651 https://www.accessdata.fda.gov/cdrh_docs/pdf20/K200441.pdf

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 Science* 2020;19:3-15.