Prostatic Urethral Lift

Medicare Advantage Medical Policy #MA-109
Original Effective Date: 07/01/2025
Current Effective Date: 07/01/2025

Applies to all products administered or underwritten by the Health Plan, unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Health Plan may consider the use of prostatic urethral lift in individuals with moderate-to-severe lower urinary tract obstruction due to benign prostatic hyperplasia when all of the following criteria are met to be **eligible for coverage:****

Patient Selection Criteria

Coverage eligibility for prostatic urethral lift will be considered when all of the following criteria are met:

- The individual has persistent or progressive lower urinary tract symptoms despite medical therapy (α_1-adrenergic antagonists maximally titrated, 5α-reductase inhibitors, or combination medication therapy maximally titrated) over a trial period of no less than 12 weeks, or is unable to tolerate medical therapy; AND,
- Prostate gland volume is ≤80 mL; AND,
- Prostate anatomy demonstrates normal bladder neck without an obstructive or protruding median lobe; AND,
- Individual does not have active urinary tract infection or recent prostatitis (within past year); AND,
- Individual has had appropriate testing to exclude diagnosis of prostate cancer; AND,
- Individual does not have a known allergy to nickel, titanium or stainless steel; AND,
- The individual is 45 years of age or older.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Health Plan considers the use of prostatic urethral lift in other situations, including repeat procedures, to be **investigational.***

The use of prostatic urethral lift when patient selection criteria are not met is considered to be **investigational.***

Background/Overview

Benign Prostatic Hyperplasia

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. The clinical manifestations of BPH include increased urinary frequency, nocturia, urgency or hesitancy to urinate, and a weak stream when urinating. The urinary tract symptoms often progress with worsening hypertrophy and may lead to acute urinary retention, incontinence, renal insufficiency, and/or urinary tract infection. Benign prostatic hyperplasia prevalence increases with age and is present in more than 80% of individuals ages 70 to 79 years.

Two scores are widely used to evaluate BPH-related symptoms: the American Urological Association Symptom Index (AUASI) and the International Prostate Symptom Score (IPSS). The AUASI is a self-administered 7-item questionnaire assessing the severity of various urinary symptoms. Total AUASI scores range from 0 to 35, with overall severity categorized as mild (≤7), moderate (8-19), or severe (20-35). The IPSS incorporates questions from the AUASI and a quality of life question or a "Bother score."

Evaluation and management of BPH include assessment for other causes of lower urinary tract dysfunction (eg, prostate cancer), symptom severity, and the degree that symptoms are bothersome to determine the therapeutic approach.

For patients with moderate-to-severe symptoms (eg, an AUASI score of ≥8), bothersome symptoms, or both, a discussion about medical therapy is reasonable. Benign prostatic hyperplasia should generally be treated medically first. Available medical therapies for BPH-related lower urinary tract dysfunction include α-adrenergic blockers (eg, alfuzosin, doxazosin, tamsulosin, terazosin, silodosin), 5α-reductase inhibitors (eg, finasteride, dutasteride), combination α-adrenergic blockers and 5α-reductase inhibitors, anti-muscarinic agents (eg, darifenacin, solifenacin, oxybutynin), and phosphodiesterase-5 inhibitors (eg, tadalafil). In a meta-analysis of both indirect comparisons from placebo-controlled studies (including 6,333 patients) and direct comparative studies (including 507 patients), Djavan et al (1999) found that the IPSS improved by 30% to 40% and the Qmax score (mean peak urinary flow rate) improved by 16% to 25% in individuals assigned to α-adrenergic blockers. Combination therapy using an α-adrenergic blocker and 5α-reductase inhibitor has been shown to be more effective for improving IPSS than either treatment alone, with median scores improving by more than 40% over 1 year and by more than 45% over 4 years.

Patients who do not have sufficient response to medical therapy, or who are experiencing significant side effects with medical therapy, may be referred for surgical or ablative therapies. Various surgical and ablative procedures are used to treat BPH. Transurethral resection of the prostate (TURP) is generally considered the reference standard for comparisons of BPH procedures. In the perioperative period, TURP is associated with risks of any operative procedure (eg, anesthesia risks, blood loss). Although short-term mortality risks are generally low, a large prospective study with 10,654 patients by Reich et al (2008) reported the following short-term complications: "failure to void (5.8%),

surgical revision (5.6%), significant urinary tract infection (3.6%), bleeding requiring transfusions (2.9%), and transurethral resection syndrome (1.4%)." Incidental carcinoma of the prostate was diagnosed by histologic examination in 9.8% of patients. In the longer term, TURP is associated with an increased risk of sexual dysfunction and incontinence.

Several minimally invasive prostate ablation procedures are available, including transurethral microwave thermotherapy, transurethral needle ablation of the prostate, urethromicroablation phototherapy, and photoselective vaporization of the prostate. The minimally invasive procedures were individually compared with TURP at the time they were developed, which provided a general benchmark for evaluating those procedures. The American Urological Association (AUA) recommends surgical intervention for patients who have "renal insufficiency secondary to BPH, refractory urinary retention secondary to BPH, recurrent urinary tract infections (UTIs), recurrent bladder stones or gross hematuria due to BPH, and/or with lower urinary tract symptoms (LUTS) attributed to BPH refractory to and/or unwilling to use other therapies."

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

One implantable transprostatic tissue retractor system has been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. In 2013, the NeoTract UroLift®‡ System UL400 (NeoTract) was cleared (after receiving clearance through the FDA's de novo classification process in March 2013; K130651/DEN130023). In 2016, the FDA determined that the UL500 was substantially equivalent to existing devices (UL400) for the treatment of symptoms of urinary flow obstruction secondary to BPH in individuals ages 50 years and older. In 2017, the FDA expanded the indication for the UL400 and UL500 to include *lateral and median* lobe hyperplasia in men 45 years or older. An additional clearance in 2019 (K193269) modified an existing contraindication for use from men with a prostate volume of >80 cc to men with a prostate volume of >100 cc. FDA product code: PEW.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Benign prostatic hyperplasia (BPH) is a common condition in older individuals that can lead to increased urinary frequency, an urgency to urinate, a hesitancy to urinate, nocturia, and a weak stream when urinating. The prostatic urethral lift (PUL) procedure involves the insertion of one or more permanent implants into the prostate, which retracts prostatic tissue and maintains an expanded urethral lumen.

Summary of Evidence
For individuals who have lower urinary tract obstruction symptoms due to benign prostatic hyperplasia (BPH) who do not have sufficient response to medical therapy or are experiencing significant side effects with medical therapy and receive a prostatic urethral lift (PUL), the evidence includes systematic reviews, randomized controlled trials (RCTs), and nonrandomized studies. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, and treatment-related morbidity. One RCT, the BPH6 study, compared the PUL procedure with transurethral resection of the prostate (TURP) and reported that the PUL procedure was noninferior for the study's composite endpoint, which required concurrent fulfillment of 6 independently validated measures of symptoms, safety, and sexual health. While TURP was superior to PUL in managing lower urinary tract symptoms, PUL did provide significant symptom improvement over 2 years. PUL was further superior to TURP in preserving ejaculatory function. These findings were corroborated by another RCT (the LIFT study), which compared PUL with sham control. Patients underwent washout of BPH medications before enrollment. LIFT reported that patients with the PUL procedure, compared with patients who had sham surgery and no BPH medication, had greater improvements in lower urinary tract symptoms without worsened sexual function at 3 months. After 3 months, patients were given the option to have PUL surgery; 80% of the patients with sham procedures chose that option. Publications from this trial reported these findings were preserved in a subset of patients over 3 to 5 years; however, a high number of patients were either excluded or lost to follow-up during this time. The BPH6 and LIFT RCTs included men with a prostate volume up to 80 cm^3 and excluded men with median lobe obstruction. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.
For individuals who have lower urinary tract obstruction symptoms due to BPH who have had a prior PUL procedure who are treated with a repeat PUL, the evidence includes long-term follow-up data from the LIFT study, systematic reviews, and reports on care setting real world experience. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, and treatment-related morbidity. Clinical data on the occurrence of repeat PUL, and consensus on clinically relevant definitions of retreatment/reintervention and subsequent outcomes are lacking. The 5 year surgical reintervention rate in the LIFT study was reported as 13.6%, while a meta-analysis concluded that the surgical reintervention rate following PUL is 6% per year. An analysis of clinical care setting real world experience reported the overall retreatment rate at 1 and 2 years to be 5.2% (95% confidence interval [CI], 4.2 to 6.1) and 11.9% (95% CI, 10.1 to 13.6), respectively, following an initial PUL. A retrospective healthcare system database analysis of endoscopic procedures for BPH found that patients treated with PUL were almost twice as likely to be retreated at 2-year follow-up compared to those receiving TURP (odds ratio [OR], 1.78; $p<.01$). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

Clinical Input from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2017
Clinical input was sought to help determine whether the use of PUL for individuals with lower urinary tract obstruction symptoms due to BPH who do not have sufficient response to medical therapy or are experiencing significant side effects with medical therapy would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, while this policy was under review in 2017, clinical input on the use of a prostatic urethral lift for 3 indications were received from 4 respondents, including 2 physician-level responses identified through a specialty society and 2 physician-level responses identified through an academic medical center. Input consistently supported that the use of PUL for individuals with moderate-to-severe lower urinary tract obstruction symptoms due to BPH provides a clinically meaningful improvement in net health outcome and indicates this use is consistent with generally accepted medical practice. See Appendices 1 and 2 for details of the clinical input.

Practice Guidelines and Position Statements
Guidelines or position statements will be considered for inclusion in ‘Supplemental Information’ if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Urological Association
In 2018, the American Urological Association published guidelines on the surgical management of LUTS attributed to BPH; the 2018 guidelines were most recently amended in 2021.. The guidelines made the following recommendations and statements regarding prostatic urethral lift (PUL).

- "PUL may be offered as an option for patients with LUTS [lower urinary tract symptoms] /BPH [benign prostatic hyperplasia] provided prostate volume 30-80cc and verified absence of an obstructive middle lobe "
    - "Moderate Recommendation; Evidence Level: Grade C indicating "Benefits > Risks/Burdens (or vice versa); Net benefit (or net harm) appears moderate. Applies to most patients in most circumstances but better evidence is likely to change confidence"
- "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 indicating "Risks/Burdens unclear; Alternative strategies may be equally reasonable. Better evidence likely to change confidence"

- "Clinicians should inform patients of the possibility of treatment failure and the need for additional or secondary treatments when considering surgical and minimally-invasive treatments for LUTS/BPH."
- "Surgery is recommended for patients who have renal insufficiency secondary to BPH, refractory urinary retention secondary to BPH, recurrent urinary tract infections (UTIs), recurrent bladder stones or gross hematuria due to BPH, and/or with LUTS/BPH refractory to or unwilling to use other therapies."

National Institute for Health and Care Excellence
In 2014, the National Institute for Health and Care Excellence published guidance on urethral lift implants to treat lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH). The guidance stated:
"Current evidence on the efficacy and safety of insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia is adequate to support the use of this procedure."

In 2021, the National Institute for Health and Care Excellence published updated guidance on the use of UroLift for treating LUTS of BPH. The guidance stated: "the UroLift system relieves lower urinary tract symptoms, avoids risk to sexual function, and improves quality of life " and "the UroLift system 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."

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date

Ongoing			
NCT06037356	Prostatic Urethral Lift Versus Transurethral Resection of Prostate in Benign Prostatic Hyperplasia Patients With Urinary Retention	100	May 2032 (recruiting)
NCT04987892[a]	Investigating Medication vs. Prostatic Urethral Lift: Assessment and Comparison of Therapies for Benign Prostatic Hyperplasia	250	Oct 2025 (recruiting)
NCT05784558[a]	RELIEF Study: Real-world Evaluation of LUTS Interventions and Patient Experience During Follow-up	2500	Dec 2030 (not yet recruiting)

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

References

1. Sarma AV, Wei JT. Clinical practice. Benign prostatic hyperplasia and lower urinary tract symptoms. N Engl J Med. Jul 19 2012; 367(3): 248-57. PMID 22808960
2. Barry MJ, Fowler FJ, O'Leary MP, et al. Measuring disease-specific health status in men with benign prostatic hyperplasia. Measurement Committee of The American Urological Association. Med Care. Apr 1995; 33(4 Suppl): AS145-55. PMID 7536866
3. O'leary MP. Validity of the "bother score" in the evaluation and treatment of symptomatic benign prostatic hyperplasia. Rev Urol. 2005; 7(1): 1-10. PMID 16985801
4. Djavan B, Marberger M. A meta-analysis on the efficacy and tolerability of alpha1-adrenoceptor antagonists in patients with lower urinary tract symptoms suggestive of benign prostatic obstruction. Eur Urol. 1999; 36(1): 1-13. PMID 10364649
5. Foster HE, Barry MJ, Dahm P, et al. Surgical Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: AUA Guideline. J Urol. Sep 2018; 200(3): 612-619. PMID 29775639
6. Reich O, Gratzke C, Bachmann A, et al. Morbidity, mortality and early outcome of transurethral resection of the prostate: a prospective multicenter evaluation of 10,654 patients. J Urol. Jul 2008; 180(1): 246-9. PMID 18499179
7. 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. Oct 2021; 206(4): 818-826. PMID 34384236
8. Sundaram D, Sankaran PK, Raghunath G, et al. Correlation of Prostate Gland Size and Uroflowmetry in Patients with Lower Urinary Tract Symptoms. J Clin Diagn Res. May 2017; 11(5): AC01-AC04. PMID 28658743
9. Rosen RC, Catania JA, Althof SE, et al. Development and validation of four-item version of Male Sexual Health Questionnaire to assess ejaculatory dysfunction. Urology. May 2007; 69(5): 805-9. PMID 17482908

10. Cappelleri JC, Rosen RC. The Sexual Health Inventory for Men (SHIM): a 5-year review of research and clinical experience. Int J Impot Res. 2005; 17(4): 307-19. PMID 15875061
11. Sønksen 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): 643-52. PMID 25937539
12. Barry MJ, Williford WO, Chang Y, et al. Benign prostatic hyperplasia specific health status measures in clinical research: how much change in the American Urological Association symptom index and the benign prostatic hyperplasia impact index is perceptible to patients?. J Urol. Nov 1995; 154(5): 1770-4. PMID 7563343
13. Roehrborn CG, Wilson TH, Black LK. Quantifying the contribution of symptom improvement to satisfaction of men with moderate to severe benign prostatic hyperplasia: 4-year data from the CombAT trial. J Urol. May 2012; 187(5): 1732-8. PMID 22425127
14. Perera M, Roberts MJ, Doi SA, et al. Prostatic urethral lift improves urinary symptoms and flow while preserving sexual function for men with benign prostatic hyperplasia: a systematic review and meta-analysis. Eur Urol. Apr 2015; 67(4): 704-13. PMID 25466940
15. Cantwell AL, Bogache WK, Richardson SF, 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. Apr 2014; 113(4): 615-22. PMID 24765680
16. Shore N, Freedman S, Gange S, et al. Prospective multi-center study elucidating patient experience after prostatic urethral lift. Can J Urol. Feb 2014; 21(1): 7094-101. PMID 24529008
17. McNicholas TA, Woo HH, Chin PT, et al. Minimally invasive prostatic urethral lift: surgical technique and multinational experience. Eur Urol. Aug 2013; 64(2): 292-9. PMID 23357348
18. Chin PT, Bolton DM, Jack G, et al. Prostatic urethral lift: two-year results after treatment for lower urinary tract symptoms secondary to benign prostatic hyperplasia. Urology. Jan 2012; 79(1): 5-11. PMID 22202539
19. Woo HH, Bolton DM, Laborde E, et al. Preservation of sexual function with the prostatic urethral lift: a novel treatment for lower urinary tract symptoms secondary to benign prostatic hyperplasia. J Sex Med. Feb 2012; 9(2): 568-75. PMID 22172161
20. Woo HH, Chin PT, McNicholas TA, et al. Safety and feasibility of the prostatic urethral lift: a novel, minimally invasive treatment for lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH). BJU Int. Jul 2011; 108(1): 82-8. PMID 21554526
21. Hoffman RM, Monga M, Elliott SP, et al. Microwave thermotherapy for benign prostatic hyperplasia. Cochrane Database Syst Rev. Sep 12 2012; (9): CD004135. PMID 22972068
22. 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): 2161-7. PMID 23764081
23. Shore N. A Review of the Prostatic Urethral Lift for Lower Urinary Tract Symptoms: Symptom Relief, Flow Improvement, and Preservation of Sexual Function in Men With Benign Prostatic Hyperplasia. Curr Bladder Dysfunct Rep. 2015; 10(2): 186-192. PMID 25984251
24. Roehrborn CG, Rukstalis DB, Barkin J, et al. Three year results of the prostatic urethral L.I.F.T. study. Can J Urol. Jun 2015; 22(3): 7772-82. PMID 26068624

25. 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. Jan 2014; 11(1): 279-87. PMID 24119101
26. Garrido Abad P, Coloma Del Peso A, Sinues Ojas B, et al. [Urolift®, a new minimally invasive treatment for patients with low urinary tract symptoms secondary to BPH. Preliminary results]. Arch Esp Urol. 2013; 66(6): 584-91. PMID 23985459
27. Jones P, Rajkumar GN, Rai BP, et al. Medium-term Outcomes of Urolift (Minimum 12 Months Follow-up): Evidence From a Systematic Review. Urology. Nov 2016; 97: 20-24. PMID 27208817
28. Bozkurt A, Karabakan M, Keskin E, et al. Prostatic Urethral Lift: A New Minimally Invasive Treatment for Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia. Urol Int. 2016; 96(2): 202-6. PMID 26613256
29. Ray A, Morgan H, Wilkes A, et al. The Urolift System for the Treatment of Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia: A NICE Medical Technology Guidance. Appl Health Econ Health Policy. Oct 2016; 14(5): 515-26. PMID 26832146
30. 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. Jun 2020; 52(6): 999-1008. PMID 32065331
31. Rukstalis D, Rashid P, Bogache WK, et al. 24-month durability after crossover to the prostatic urethral lift from randomised, blinded sham. BJU Int. Oct 2016; 118 Suppl 3: 14-22. PMID 27684483
32. Sievert KD, Schonthaler M, Berges R, et al. Minimally invasive prostatic urethral lift (PUL) efficacious in TURP candidates: a multicenter German evaluation after 2 years. World J Urol. Jul 2019; 37(7): 1353-1360. PMID 30283994
33. 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. May 25 2019; 5(5): CD012832. PMID 31128077
34. 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. May 2017; 119(5): 767-775. PMID 27862831
35. Franco JVA, Jung JH, Imamura M, et al. Minimally invasive treatments for benign prostatic hyperplasia: a Cochrane network meta-analysis. BJU Int. Aug 2022; 130(2): 142-156. PMID 34820997
36. Roehrborn CG. Prostatic Urethral Lift: A Unique Minimally Invasive Surgical Treatment of Male Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia. Urol Clin North Am. Aug 2016; 43(3): 357-69. PMID 27476128
37. 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
38. 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. Sep 2019; 22(3): 411-419. PMID 30542055

39. Eure G, Rukstalis D, Roehrborn C. Prostatic Urethral Lift for Obstructive Median Lobes: Consistent Results Across Controlled Trial and Real-World Settings. J Endourol. Jan 2023; 37(1): 50-59. PMID 35876440
40. Shah BB, Tayon K, Madiraju S, et al. Prostatic Urethral Lift: Does Size Matter?. J Endourol. Jul 2018; 32(7): 635-638. PMID 29631445
41. 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. Jul 2019; 33(7): 576-584. PMID 31115257
42. Kaplan SA. Surgical Reintervention Rate after Prostatic Urethral Lift: Systematic Review and Meta-Analysis Involving over 2,000 Patients. Letter. J Urol. Mar 2021; 205(3): 939-940. PMID 33393811
43. 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. Reply. J Urol. Mar 2021; 205(3): 940-941. PMID 33393812
44. McVary KT, Kaplan SA. A Tower of Babel in Today's Urology: Disagreement in Concepts and Definitions of Lower Urinary Tract Symptoms/Benign Prostatic Hyperplasia Re-Treatment. J Urol. Aug 2020; 204(2): 213-214. PMID 32469261
45. Shin BNH, Qu L, Rhee H, et al. Systematic review and network meta-analysis of re-intervention rates of new surgical interventions for benign prostatic hyperplasia. BJU Int. Aug 2024; 134(2): 155-165. PMID 38600763
46. 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. Nov 2020; 204(5): 1019-1026. PMID 32396049
47. Gaffney CD, Basourakos SP, Al Hussein Al Awamlh B, et al. Adoption, Safety, and Retreatment Rates of Prostatic Urethral Lift for Benign Prostatic Enlargement. J Urol. Aug 2021; 206(2): 409-415. PMID 33793296
48. Page T, Veeratterapillay R, Keltie K, et al. Prostatic urethral lift (UroLift): a real-world analysis of outcomes using hospital episodes statistics. BMC Urol. Apr 07 2021; 21(1): 55. PMID 33827525
49. National Institute for Health and Care Excellence (NICE). Insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia [IPG475]. 2014; https://www.nice.org.uk/guidance/ipg475/chapter/1-recommendations.
50. National Institute for Health and Care Excellence (NICE). UroLift for treating lower urinary tract symptoms of benign prostatic hyperplasia [MTG58]. 2021; https://www.nice.org.uk/guidance/MTG58.

Policy History

Original Effective Date: 07/01/2025
Current Effective Date: 07/01/2025
04/15/2025 Utilization Management Committee review/approval. New policy.
Next Scheduled Review Date: 04/2026

Coding

The five character codes included in the Health Plan Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2025 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of the Health Plan Medical Policy Coverage Guidelines is with the Health Plan and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in the Health Plan Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of the Health Plan Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	52441, 52442
HCPCS	C9739, C9740
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the Health Plan's Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Health Plan recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

Medicare Advantage Members

Established coverage criteria for Medicare Advantage members can be found in Medicare coverage guidelines in statutes, regulations, National Coverage Determinations (NCD)s, and Local Coverage

Determinations (LCD)s. To determine if a National or Local Coverage Determination addresses coverage for a specific service, refer to the Medicare Coverage Database at the following link: https://www.cms.gov/medicare-coverage-database/search.aspx. You may wish to review the Guide to the MCD Search here: https://www.cms.gov/medicare-coverage-database/help/mcd-benehelp.aspx.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, internal coverage criteria may be developed. This policy is to serve as the summary of evidence, a list of resources and an explanation of the rationale that supports the adoption of this internal coverage criteria.

InterQual®
Interqual® is utilized as a source of medical evidence to support medical necessity and level of care decisions. InterQual® criteria are intended to be used in connection with the independent professional medical judgment of a qualified health care provider. InterQual® criteria are clinically based on best practice, clinical data, and medical literature. The criteria are updated continually and released annually. InterQual® criteria are a first-level screening tool to assist in determining if the proposed services are clinically indicated and provided in the appropriate level or whether further evaluation is required. The utilization review staff does the first-level screening. If the criteria are met, the case is approved; if the criteria are not met, the case is referred to the medical director.