

02-54000-21

Original Effective Date: 03/15/05

Reviewed: 09/28/23

Revised: 03/15/24

Subject: Temporary Prostatic Urethral Stents (Including Implantable Nitinol Devices) and Prostatic Urethral Lift

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

[Position Statement](#)

[Billing/Coding](#)

[Reimbursement](#)

[Program
Exceptions](#)

[Definitions](#)

[Related Guidelines](#)

[Other](#)

[References](#)

[Updates](#)

DESCRIPTION:

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. Several procedures have been investigated as a minimally invasive treatment for lower urinary tract symptoms associated with BPH such as temporary prostatic urethral stents and the prostatic urethral lift.

Temporary prostatic urethral stents, including temporary implanted nitinol devices, have been investigated as a short-term treatment option. Devices such as the Spanner™ (Abbeymoore Medical) and the iTind System (Olympus) have been granted premarket approval from the U.S. Food and Drug Administration (FDA). The Spanner device is inserted under topical anesthesia and is intended for temporary use (up to 30 days) to maintain urine flow and allow voluntary urination in patients following minimally invasive treatment for BPH and after initial post-treatment catheterization. With the use of a rigid cystoscope, the iTind System is temporarily implanted into the obstructed prostatic urethra where 3 double intertwined nitinol struts configured in a tulip shape gradually expand. The resulting circumferential force facilitates tissue reshaping via ischemic necrosis of the mucosa, resulting in urethral expansion and prostatic incisions that function as longitudinal channels to improve urine outflow. The implant is typically removed after 5 to 7 days of treatment.

The prostatic urethral lift procedure is another procedure that involves the placement of 1 or more implants in lobes of the prostate using a transurethral delivery device. The implant device is designed to retract the prostate to allow expansion of the prostatic urethra. The implants are retained in the prostate to maintain an expanded urethral lumen. One device, the NeoTract® UroLift® System, has been cleared for marketing by the FDA.

POSITION STATEMENT:

Use of prostatic urethral lift in members with moderate-to-severe lower urinary tract obstruction due to benign prostatic hyperplasia, including lateral and median lobe hyperplasia, **meets the definition of medical necessity** when **ALL** of the following criteria are met:

1. Member has persistent or progressive lower urinary tract symptoms despite medical therapy over a trial period of no less than 4 weeks, or is unable to tolerate medical therapy;
2. Prostate gland volume is ≤ 100 mL (or cc)
3. Member does not have urinary retention related to conditions other than benign prostatic hyperplasia, urinary tract infection, or recent prostatitis (within past year) and
4. Member does not have a known allergy to nickel, titanium or stainless steel.

Use of prostatic urethral lift in all other situations is considered **experimental or investigational**. The evidence is insufficient to determine the effects of the technology on health outcomes.

Use of a temporary prostatic urethral stent, including an implantable nitinol device (iTind), is considered **experimental or investigational** for all indications. The evidence is insufficient to determine the effects of the technology on health outcomes.

BILLING/CODING INFORMATION

CPT Coding

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)
53855	Insertion of a temporary prostatic urethral stent, including urethral measurement (Investigational)

HCPCS Coding

C9739	Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants
C9740	Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants
C9769	Cystourethroscopy, with insertion of temporary prostatic implant/stent with fixation/anchor and incisional struts (Investigational)

ICD-10 Diagnosis Codes That Support Medical Necessity:

N40.1	Benign prostatic hyperplasia with lower urinary tract symptoms
-------	--

REIMBURSEMENT INFORMATION:

Refer to section entitled [POSITION STATEMENT](#).

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline reviewed date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at [Coverage Protocol Exemption Request](#)

DEFINITIONS:

No guideline specific definitions apply.

RELATED GUIDELINES:

None.

OTHER:

None.

REFERENCES:

1. Abdul-Muhsin HM, Jakob NJ, et al. Infectious complications associated with the use of temporary prostatic urethral stents in patients with benign prostatic hyperplasia. *Can J Urol*. 2016 Oct;23(5):8465-8470. PMID: 27705732.
2. American Urological Association (AUA). AUA Guideline: Management of Benign Prostatic Hyperplasia (BPH)- Chapter 1: Diagnosis and Treatment Recommendations; accessed at auanet.org.
3. Amparore D, De Cillis S, et al. Temporary implantable nitinol device for benign prostatic hyperplasia-related lower urinary tract symptoms: over 48-month results. *Minerva Urol Nephrol*. 2023 Dec;75(6):743-751. PMID: 37350585.
4. Barkin J, Giddens J, et al, UroLift system for relief of prostate obstruction under local anesthesia. *Can J Urol*. 2012 Apr;19(2):6217-22.
5. Blue Cross Blue Shield Association Evidence Positioning System®. 7.01.151 Prostatic Urethral Lift, 09/23.

6. Blue Cross Blue Shield Association Evidence Positioning System®; 7.01.175 Temporarily Implanted Nitinol Device (iTind) for Benign Prostatic Hyperplasia, 02/24.
7. Cantwell AL, Bogache WK, 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.
8. Carter HB, Albertsen PC, et al. Early Detection of Prostate Cancer (2018). Early detection of prostate cancer: AUA Guideline. *J Urol* 2013; 190: 419.
9. Cornu JN, Zantek P, et al. Minimally Invasive Treatments for Benign Prostatic Obstruction: A Systematic Review and Network Meta-analysis. *Eur Urol.* 2023 Jun;83(6):534-547. PMID: 36964042.
10. Dineen MK, Shore ND, Lumerman JH, et al, Use of a Temporary Prostatic Stent After Transurethral Microwave Thermotherapy Reduced Voiding Symptoms and Bother Without Exacerbating Irritative Symptoms, *Urology*, 2008 May; 71(5): 873-7.
11. Eure G, Gange S, 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.
12. Foster HE, Barry MJ, et al. Surgical Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: AUA Guideline. *J Urol.* 2018 Sep;200(3):612-619.
13. Franco JVA, Tesolin P, Jung JH. Update on the management of benign prostatic hyperplasia and the role of minimally invasive procedures. *Prostate Int.* 2023 Mar;11(1):1-7. doi: 10.1016/j.pnrl.2023.01.002.
14. Goh M, Kastner C, et al, First Experiences with the Spanner™ Temporary Prostatic Stent for Prostatic Urethral Obstruction, *Urol Int.* 2013;91(4):384-90.
15. Gratzke C, Barber N, et al, Prostatic urethral lift vs transurethral resection of the prostate: 2-year results of the BPH6 prospective, multicentre, randomized study. *BJU Int.* 2016 Nov 14. doi: 10.1111/bju.13714.
16. Grimsley SJ, Khan, MH, Lennox E, Paterson PH, Experience with the Spanner Prostatic Stent in Patients Unfit for Surgery: An Observational Study, *Journal of Endourology*, 09/01/07, 21(9): 1093-1096.
17. Jung JH, Reddy B, et al. 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.
18. Kaplan SA. Surgical Reintervention Rate after Prostatic Urethral Lift: Systematic Review and Meta-Analysis Involving over 2,000 Patients. *Letter. Urol.* Mar 2021; 205(3): 939-940.
19. Kessar D, Bellas A. Temporary prostatic stents as a replacement for urinary catheters following transurethral microwave thermotherapy: A retrospective review. *Cogent Medicine* (2017), 4: 1349355. McKenzie P, Badlani G, Critical Appraisal of the Spanner™ Prostatic Stent in the Treatment of Prostatic Obstruction, *Medical Devices: Evidence and Research*, 2011:4 27-33.
20. Lerner LB, McVary KT, et al. Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: AUA Guideline Part I-Initial Work-up and Medical Management. *J Urol.* 2021 Oct;206(4):806-817.
21. McNicholas TA, Benign prostatic hyperplasia and new treatment options - a critical appraisal of the UroLift system. *Med Devices (Auckl).* 2016 May 19;9:115-23.
22. McNicholas TA, Woo HH, et al, Minimally invasive prostatic urethral lift: surgical technique and multinational experience. *Eur Urol.* 2013 Aug;64(2):292-9.
23. McVary KT, Dahm P, et al. Surgical Management Of Lower Urinary Tract Symptoms Attributed To Benign Prostatic Hyperplasia:AUA Guideline Amendment 2019. *J Urol.* 2019 May 6:101097JU0000000000000319.

24. McVary KT. Surgical treatment of benign prostatic hyperplasia (BPH). In: UpToDate, O'Leary MP, Chen W (Eds), UpToDate, Waltham, MA; accessed at uptodate.com.
25. McVary KT, Gange SN, 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.
26. Miller LE, Chughtai B, 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.
27. Miller LE, Chughtai B, 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.
28. National Institute for Health and Care Excellence (NICE). Interventional procedures guidance: prostatic urethral temporary implant insertion for lower urinary tract symptoms caused by benign prostatic hyperplasia [IPG737]. September 21, 2022; access at nice.org.uk.
29. National Institute for Health and Care Excellence (NICE). UroLift for treating lower urinary tract symptoms of benign prostatic hyperplasia. Medical technologies guidance [MTG58], Published: 04 May 2021; accessed at nice.org.uk.
30. Nguyen AV, Verma I, et al. A scoping review of office-based prostatic stents: past, present, and future of true minimally invasive treatment of benign prostatic hyperplasia. *World J Urol.* 2023 Nov;41(11):2925-2932. PMID: 37479913.
31. Page T, Veeratterapillay R, et al. Prostatic urethral lift (UroLift): a real-world analysis of outcomes using hospital episodes statistics. *BMC Urol.* Apr 07 2021; 21(1): 55.
32. Parsons JK, Dahm P, et al. Benign Prostatic Hyperplasia: Surgical Management of Benign Prostatic Hyperplasia/Lower Urinary Tract Symptoms, 2020; accessed at auanet.org.
33. Ray A, Morgan H, 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.* 2016 Oct;14(5):515-26.
34. Roach RM. Treating male retention patients with temporary prostatic stent in a large urology group practice. *Can J Urol.* 2017 Apr;24(2):8776-8781.PMID: 28436369.
35. Roehrborn CG, Barkin J, 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.
36. Roehrborn CG, Chin PT, Woo HH. The UroLift implant: mechanism behind rapid and durable relief from prostatic obstruction. *Prostate Cancer Prostatic Dis.* 2021 Aug 6.
37. 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.* 2016 Aug;43(3):357-69.
38. Roehrborn CG, et al, Three Year Results of the Prostatic Urethral L.I.F.T Study, *Can J Urol.* 2015 Jun;22(3):7772-82.
39. Roehrborn CG, Chin PT, Woo HH. The UroLift implant: mechanism behind rapid and durable relief from prostatic obstruction. *Prostate Cancer Prostatic Dis.* 2021 Aug 6. PMID:34363010.
40. Roehrborn CG, Gange SN, et al, Durability of the prostatic urethral lift: two year results of the L.I.F.T. Study. *Urology Practice* 2015 (2); 1-7.
41. Roehrborn CG, Gange SN, 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.
42. Rukstalis D, Grier D, et al. Prostatic Urethral Lift (PUL) for obstructive median lobes: 12 month results of the MedLift Study. *Prostate Cancer Prostatic Dis.*, 2018 Dec 12. PMID 30542055.

43. Sabharwal S. Sabharwal S. Using Temporary Prostatic Stents to Eliminate Bacterial Colonization in Men with Chronic Indwelling Catheters: A Pilot Study. *Cureus*. 2018 Aug; 10(8): e3152.
44. Sandhu JS, Bixler BR, et al. Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia (BPH): AUA Guideline Amendment 2023. *J Urol*. 2024 Jan;211(1):11-19. doi: 10.1097/JU.0000000000003698. Epub 2023 Sep 14.
45. 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*; published online: 27 March 2015.
46. Shore N, Freedman S, et al, Prospective multi-center study elucidating patient experience after prostatic urethral lift. *Can J Urol*. 2014 Feb.
47. Sievert KD, Schonhaler 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.
48. Sønksen J, Barber NJ, et al, Prospective, Randomized, Multinational Study of Prostatic Urethral Lift Versus Transurethral Resection of the Prostate: 12-month Results from the BPH6 Study. *European Urology* (2015); <http://dx.doi.org/10.1016/j.eururo.2015.04.024>.
49. Sountoulides P, Karatzas A, Gravas S. Current and emerging mechanical minimally invasive therapies for benign prostatic obstruction. *Ther Adv Urol*. 2019 Feb 14;11:1756287219828971.
50. Tanneru K, Gautam S, 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.
51. Temporary Prostatic Stent The Spanner® Clinical Dossier, 2019.
52. U.S. Food and Drug Administration (FDA), accessed at fda.gov.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 02/22/24.

GUIDELINE UPDATE INFORMATION:

03/15/05	New Medical Coverage Guideline.
03/15/06	Annual review: continue investigational.
02/15/07	Scheduled review. No change in investigational status. Revised when services are covered; add “of temporary prostatic stent”. Added “temporary prostatic” to Billing/Coding Information section-ICD-9 diagnoses codes that support medical necessity. Updated references.
06/15/07	Reformatted guideline; references updated.
03/15/08	Annual review: position statement maintained, description section updated, references updated.
03/15/09	Annual review: position statement maintained and references updated.
01/01/10	Annual HCPCS coding update: added code 53855, deleted code 0084T.
03/15/10	Annual review: position statement maintained; description section and references updated.
02/15/11	Annual review: position statement maintained and references updated.

10/15/11	Scheduled review; position statement maintained, description section and references updated.
11/15/12	Annual review; position statement maintained and references updated.
09/15/13	Annual review; investigational position statement maintained and references updated.
08/15/14	Annual review; position statement maintained and references updated.
06/15/15	Annual review; position statement, billing/coding, description, guideline title and references updated.
04/15/16	Revision; position statements maintained and references updated
05/15/17	Revision; Investigational position statements maintained; description and references updated.
02/15/18	Annual review; PUL coverage statement added; description, coding, & references updated.
10/15/18	Review; Coverage criteria and references updated.
10/15/19	Review; <i>Prostate-specific antigen level ≥ 3 ng/mL</i> removed from PUL criteria; investigational temporary prostatic stent position maintained; and references updated.
10/01/20	Quarterly CPT/HCPCS coding update; added code C9769.
10/15/20	Review; Investigational position statement and references updated.
10/15/21	Review: Position statement and references updated.
10/25/21	Revision: Position statement updated.
03/15/22	Review: PUL criteria updated; references updated.
05/25/23	Update to Program Exceptions section.
10/15/23	Review: Position statement and references updated.
03/15/24	Revision: Position statement, references, and policy title updated.