



Clinical Policy: Prostatic Urethral Lift

Reference Number: HNCA.CP.MP.537

Effective Date: 09/14

Last Review Date: 09/19

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

The UroLift System (NeoTract Inc.) is a minimally invasive, prostatic urethral lift (PUL) system that provides anterolateral mechanical traction of the lateral lobes of the prostate, opening the urethral lumen, and reducing urinary obstruction. The system is proposed as a minimally invasive treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men age 45 and older. This policy addresses the medical necessity criteria for prostatic urethral lift.

Policy/Criteria

It is the policy of Health Net of California that prostatic urethral lift (i.e., UroLift System) is **medically necessary** for treatment of men with moderate to severe symptomatic benign prostatic hyperplasia with urinary outflow tract symptoms who meet all of the following criteria:

- A. Age 45 and older
- B. Refractory to or intolerant of usual medical management
- C. Prostate volume <80ml
- D. Median lobe of prostate is not obstructed or protruding
- E. Absence of urinary tract infection, gross hematuria or urinary incontinence
- F. No urethral condition that may prevent insertion of delivery system into the bladder
- G. No known allergy to nickel or other metals.

Background

Benign prostatic hyperplasia (BPH) is an enlargement or growth of the prostate that often occurs as men age. The enlarged prostate restricts the urethra and applies pressure on the base of the bladder leading to lower urinary tract symptoms (LUTS) such as increased frequency of urination, nocturia, hesitancy, urgency, and weak urinary stream. Although LUTS secondary to BPH is not usually life-threatening, it can significantly impact the quality of life. Treatment goals include reducing symptoms, alteration of disease progression and prevention of complications that can be associated with BPH/LUTS. Symptomatic patients may benefit from medical or surgical treatment (e.g., transurethral resection of the prostate, open prostatectomy etc.)

The UroLift System, a prostatic urethral lift (PUL) system, is proposed as a minimally invasive option to treat BPH. The UroLift System is composed of two main components: the UroLift Delivery Device and UroLift Implant. The delivery device contains a preloaded implant that deploys, self-adjusts, tensions, and trims a permanent tensioning suture. The suture runs from the urethra to the outer prostatic capsule and serves to compress the lateral lobe of the prostate. Implants are delivered bilaterally to separate the encroaching lobes. Four to 5 implants are typically inserted, but this varies with the size and shape of the prostate.



CLINICAL POLICY

Prostatic Urethral Lift

Three year results of a multi-center, randomized, patient and outcome assessor blinded 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.¹ Several other trials reported similar results, noting PUL improves LUTS and urinary flow while preserving erectile and ejaculatory function.

FDA Approval

In 2013, the NeoTract UroLift® System UL400 (NeoTract) was cleared (after receiving clearance through FDA's de novo classification process in March 2013). In 2016, 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, FDA expanded the indication for the UL400 and UL500 to include lateral and median lobe hyperplasia in men 45 years or older

American Urological Association

The most current American Urological Association (AUA) guideline on the surgical management of BPH was published in 2018 noting:

“Clinicians should consider PUL [prostatic urethral lift] as an option for patients with LUTS [lower urinary tract symptoms] attributed to BPH [benign prostatic hyperplasia] provided prostate volume <80g and verified absence of an obstructive middle lobe; however, patients should be informed that symptom reduction and flow rate improvement is less significant compared to TURP [transurethral resection of the prostate].”

National Institute of Health and Care Excellence (NICE)

Medical Technologies Guidance on UroLift for treating lower urinary tract symptoms of benign prostatic hyperplasia concludes that UroLift system should be considered as an alternative to current surgical procedures for use in a daycase setting in men with lower urinary tract symptoms of BPH who are aged 50 years and older and who have a prostate of less than 100 ml without an obstructing middle lobe.³

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2015, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.



CLINICAL POLICY
Prostatic Urethral Lift

CPT® Codes	Description
52441	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant
52442	each additional permanent adjustable transprostatic implant

HCPCS Codes	Description
C9739	Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants
C9740	Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

ICD-10-CM Code	Description
N40.1	Enlarged prostate with lower urinary tract symptoms
N40.3	Nodular prostate with lower urinary tract symptoms
N41.0-N41.9	Inflammatory disease of prostate

Reviews, Revisions, and Approvals	Date	Approval Date
Policy adopted from Health Net NMP537 Prostatic Urethral Lift	9/16	
Update no changes	9/17	9/17
Update no changes	9/18	
Revised age, clarified symptoms of urinary tract outflow symptoms, updated statement by the references AUA, updated references	9/19	9/19

References

1. Roerborn CG, Rukstalis DB, Barkin J, et al. Three year results of the prostatic urethral L.I.F.T. study. Canadian Journal of Urology. 22(3); June 2015.
2. American Urological Association. Guideline:Management of Benign Prostatic Hypertrophy Available at: <https://www.auanet.org/education/guidelines/benign-prostatic-hyperplasia.cfm>
2. American Urological Association (AUA). Transprostatic Implant Appeal. Available at: <https://www.auanet.org/common/pdf/practices-resources/coding-tips/appeal-letters/2015-Transprostatic-Implant-Appeal.pdf>
3. National Institute of Health and Care Excellence (NICE). Medical Technologies guidance (MTG26). UroLift for treating lower urinary tract symptoms of benign prostatic hyperplasia. Sept. 2015. Available at: <https://www.nice.org.uk/guidance/mtg26?unlid=53953512120164702514>
4. 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.



CLINICAL POLICY
Prostatic Urethral Lift

5. Perera M, Roberts MJ, Doi SA, Bolton D. 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* 2015; 67:704.
6. Shore N, Freedman S, Gange S, et al. Prospective multi-center study elucidating patient experience after prostatic urethral lift. *Canadian Journal of Urology*. 21 (1) (pp 7094-7101), 2014.
7. 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.
8. 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*. 2015 Oct;68(4):643-52.
9. Hayes Health Technology Brief. UroLift System (NeoTract Inc.) for Treatment of Benign Prostatic Hyperplasia. July 2016
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; 190:2161.
11. 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* 2014; 113:615.
12. Foster HE, Barry MJ, Dahm P, et al. Surgical management of lower urinary tract symptoms attributed to benign prostatic hyperplasia: AUA Guideline. *J Urol*. Jun 11 2018. PMID 29775639

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy,



CLINICAL POLICY
Prostatic Urethral Lift

contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

©2016 Centene Corporation. All rights reserved. All materials are exclusively owned by Centene Corporation and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise



Health Net®

CLINICAL POLICY
Prostatic Urethral Lift

published without the prior written permission of Centene Corporation. You may not alter or remove any trademark, copyright or other notice contained herein. Centene® and Centene Corporation® are registered trademarks exclusively owned by Centene Corporation.