

**EVIDENCE-BASED CRITERIA  
SECTION: SURGERY**

**ORIGINAL EFFECTIVE DATE: 09/19/22  
LAST REVIEW DATE: 08/16/22  
CURRENT EFFECTIVE DATE: 09/19/22  
LAST CRITERIA REVISION DATE:  
ARCHIVE DATE:**

**NEXT ANNUAL REVIEW DATE: 3RD QTR 2023**

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## **PROSTATIC URETHRAL LIFT**

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**Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.**

**Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Evidence-Based Criteria must be read in its entirety to determine coverage eligibility, if any.**

**This Evidence-Based Criteria provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.**

**The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.**

**The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.**

**State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.**

**Evidence-Based Criteria are subject to change as new information becomes available.**

**For purposes of this Evidence-Based Criteria, the terms "experimental" and "investigational" are considered to be interchangeable.**

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## **PROSTATIC URETHRAL LIFT (cont.)**

### **Description:**

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.

The NeoTract UroLift® System UL400, an implantable transprostatic tissue retractor system, has received FDA approval through the 510(k) process.

### **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 ( $\leq 7$ ), 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 individuals with moderate-to-severe symptoms (eg, an AUASI score of  $\geq 8$ ), 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  $\alpha$ -adrenergic blockers (eg, alfuzosin, doxazosin, tamsulosin, terazosin, silodosin), 5 $\alpha$ -reductase inhibitors (eg, finasteride, dutasteride), combination  $\alpha$ -adrenergic blockers and 5 $\alpha$ -reductase inhibitors, anti-muscarinic agents (eg, darifenacin, solifenacin, oxybutynin), and phosphodiesterase-5 inhibitors (eg, tadalafil).

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## PROSTATIC URETHRAL LIFT (cont.)

### Criteria:

- Use of prostatic urethral lift in individuals with moderate-to-severe lower urinary tract obstruction due to benign prostatic hyperplasia is considered **medically necessary** with documentation of **ALL** of the following:
  1. The individual has persistent or progressive lower urinary tract symptoms despite medical therapy ( $\alpha$ 1-adrenergic antagonists maximally titrated, 5 $\alpha$ -reductase inhibitors, or combination medication therapy maximally titrated) over a trial period of no less than 6 months, or is unable to tolerate medical therapy
  2. Prostate gland volume is  $\leq 80$  mL
  3. Prostate anatomy demonstrates normal bladder neck without an obstructive or protruding median lobe
  4. Individual does not have urinary retention, urinary tract infection, or recent prostatitis (within past year)
  5. Individual has had appropriate testing to exclude diagnosis of prostate cancer
  6. Individual does not have a known allergy to nickel, titanium or stainless steel
- Use of prostatic urethral lift for all other indications not previously listed or if above criteria not met is considered **experimental or investigational** when any **ONE** or more of the following criteria are met:
  1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
  3. Insufficient evidence to support improvement outside the investigational setting.

These indications include, *but are not limited to*:

- Repeat procedures
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## **PROSTATIC URETHRAL LIFT (cont.)**

### **Resources:**

**Literature reviewed 08/16/22. We do not include marketing materials, poster boards and non-published literature in our review.**

1. Barry MJ, Fowler FJ, Jr., O'Leary MP, Bruskewitz RC, Holtgrewe HL, Mebust WK. 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.
2. 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. doi:10.1016/s0022-5347(01)66780-6
3. Bozkurt A, Karabakan M, Keskin E, Hirik E, Balci MB, Nuhoglu B. 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. doi:10.1159/000441850
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5. Cappelleri JC, Rosen RC. The Sexual Health Inventory for Men (SHIM): a 5-year review of research and clinical experience. *Int J Impot Res*. Jul-Aug 2005;17(4):307-19. doi:10.1038/sj.ijir.3901327
6. 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. doi:10.1016/j.urology.2011.10.021
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8. 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. doi:10.1089/end.2019.0167
9. 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. doi:10.1016/j.juro.2018.05.048

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## PROSTATIC URETHRAL LIFT (cont.)

### Resources: (cont.)

10. Garrido Abad P, Coloma Del Peso A, Sinues Ojas B, Fernández Arjona M. [Urolift®, a new minimally invasive treatment for patients with low urinary tract symptoms secondary to BPH. Preliminary results]. *Arch Esp Urol*. Jul-Aug 2013;66(6):584-91. Urolift®, un nuevo tratamiento mínimamente invasivo para los síntomas de tracto urinario inferior secundarios a HBP. Resultados preliminares.
11. 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 international*. May 2017;119(5):767-775. doi:10.1111/bju.13714
12. Hoffman RM, Monga M, Elliott SP, et al. Microwave thermotherapy for benign prostatic hyperplasia. *Cochrane Database Syst Rev*. Sep 12 2012;(9):Cd004135. doi:10.1002/14651858.CD004135.pub3
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18. 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. doi:10.1111/jsm.12333
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## PROSTATIC URETHRAL LIFT (cont.)

### Resources: (cont.)

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21. Miller LE, Chughtai B, Dornbier RA, McVary KT. 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. doi:10.1097/ju.0000000000001132
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30. 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. doi:10.1016/j.juro.2013.05.116

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## PROSTATIC URETHRAL LIFT (cont.)

### Resources: (cont.)

31. 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.
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38. 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. *Current bladder dysfunction reports*. 2015;10(2):186-192. doi:10.1007/s11884-015-0296-5
39. 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.
40. Sievert KD, Schonthalder 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. doi:10.1007/s00345-018-2494-1
41. 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. doi:10.1016/j.eururo.2015.04.024

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## **PROSTATIC URETHRAL LIFT (cont.)**

### **Resources:** (cont.)

42. 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. doi:10.7860/jcdr/2017/26651.9835
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### **Coding:**

CPT: 52441, 52442  
 HCPCS: C9739, C9740

### **History:**

### **Date:**

### **Activity:**

Medical Policy Panel

08/16/22

Approved guideline (Effective 9/19/22)

### **Policy Revisions:**





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## PROSTATIC URETHRAL LIFT (cont.)

### Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, [crc@azblue.com](mailto:crc@azblue.com). You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

### Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Dii kwe'é atah nilinigií Blue Cross Blue Shield of Arizona haada yit'éego bina'idilkidgo éi doodago Háida bíjá anilyeedigií t'áadoo le'é yina'idilkidgo beehaz'áanii hólo dii t'áa hazaadk'ehjí háká a'doowolgo bee haz'á doo baqah ilinígóo. Ata' halne'ígíí kójj' bich'í' hodílnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.



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