Prostatic Urethral Lift (Urolift)

Policy Number:	**M20171030052**
Effective Date:	**12/1/2017**
Sponsoring Department:	**Health Care Services**
Impacted Department(s):	**Health Care Services**

Type of Policy: ☒ Internal ☒ External

Data Classification: ☐Confidential ☐Restricted ☒Public

Applies to (Line of Business):

☐ Corporate (All)
☒ State Products, if yes which plan(s): ☒MediSource; ☒ MediSource Connect; ☐Child Health Plus ☒Essential Plan
☒ Medicare, if yes, which plan(s): ☒MAPD; ☐PDP; ☒ISNP; ☒CSNP
☒ Commercial, if yes, which type: ☒Large Group; ☒Small Group; ☒Individual
☒ Self-Funded Services *(Refer to specific Summary Plan Descriptions (SPDs) to determine any pre-authorization or pre-certification requirements and coverage limitations. In the event of any conflict between this policy and the SPD of a Self-Funded Plan, the SPD shall supersede the policy.)*

Excluded Products within the Selected Lines of Business (LOB)

Applicable to Vendors? Yes ☐ No☒

Purpose and Applicability:

To set forth the medical necessity criteria for **prostatic urethral lift (PUL)** for the treatment of **benign prostatic hyperplasia (BPH)** utilizing the **Urolift** implant.

Policy:

Commercial, Self-Funded and Medicare Advantage:
The prostatic urethral lift procedure is considered reasonable and necessary when the ALL of the following criteria are met:

- The UroLift device is used for the treatment of symptomatic BPH in a member with well documented voiding symptoms consistent with prostatic hyperplasia; **and**
- The member has had an adequate trial of, but is refractory to or intolerant of, usual BPH medication; **and**
- The prostate volume is less than or equal to 100 cc lateral and median lobe hyperplasia; **and**
- There are no signs, symptoms, or diagnostic evidence of an active urinary infection and no history of bacterial prostatitis in the past three (3) months; **and**
- The member is a poor candidate for other surgical interventions for BPH due to underlying disease (e.g., cardiac disease, pulmonary disease, etc.) and/or at high risk of bleeding and/or the member has opted for PUL based on likelihood of preserving sexual function and/or there is another documented reason for opting for PUL; **and**
- The member does not have a known allergy to nickel.

Limitations:

Coverage is for surgical intervention with up to a total of six implants. Implants in excess of six will deny but may be reconsidered on an exception basis with a formal redetermination.

The member's medical record should clearly document:

- Trial(s) of medical therapy attempted and reason for discontinuation or reason member is not suitable candidate for the usual BPH medication(s);
- Prostatic volume as measured by ultrasound;
- Absence of obstructive median lobe;
- BPH symptoms and AUASI score;
- Rationale for choosing PUL (e.g., chart notation indicating patient preferred PUL over TURP because of concerns about sexual function).

MediSource, MediSource Connect, and Essential Plan:
MediSource, MediSource Connect and Essential Plan cover prostatic urethral lift (PUL) for the treatment of benign prostatic hyperplasia (BPH) with the Urolift implant utilizing the criteria above.

Background:
Benign prostatic hyperplasia (BPH) is a common age-related noncancerous condition in men that is characterized by enlargement of the prostate gland which may cause symptoms of urinary outlet obstruction. Symptoms typically include increased urinary frequency, urgency, incontinence, straining; nocturia; decreased and intermittent force of the stream; hematuria; and the sensation of incomplete bladder emptying. BPH and associated lower urinary tract symptoms may result in decreased quality of life (QOL) and depression. These symptoms, especially nocturia, can lead to an increased risk of falls and fractures. Men with advanced BPH may develop recurrent urinary tract infections (UTIs), gross

hematuria, bladder calculi, or renal insufficiency. Since BPH is a progressive enlargement, treatment usually starts with conservative management (e.g., avoid diuretics at night to reduce nocturia) and progresses to medical management with pharmacotherapy (e.g., alpha-blockers, 5-alpha-reductase inhibitors) and if medication management is not sufficient, surgical intervention. Current surgical treatment of BPH involves a transurethral resection of the prostate (TURP) requiring general or spinal anesthesia and inpatient hospitalization. TURP is associated with measurable complications, including sexual dysfunction, ejaculatory dysfunction, erectile dysfunction, urinary incontinence, bladder neck contractures, urethral stricture, and septic shock.

The UroLift System (NeoTract Inc.) received de novo classification through the de novo regulatory pathway for novel low-risk medical devices on March 7, 2013. It was classified as a class II device, including both the delivery system and implant. The Urolift procedure is performed transurethrally with the patient under local or general anesthesia. A pre-loaded delivery device is passed through a rigid sheath under cystoscopic visualization. The implant provides anterolateral mechanical traction of the lateral lobes of the prostate, opening the urethral lumen, and reducing urinary obstruction. Four to five implants are typically inserted, but this varies with the size and shape of the prostate. The available evidence suggests that the UroLift does not appear to compromise sexual function, which is an advantage of the implant compared with the standard BPH treatment, TURP. At this time, a there is low-quality body of evidence suggesting that the UroLift may improve the LUTS associated with BPH, however uncertainty remains due to the lack of comparative studies and the limited long-term evidence regarding the durability and safety of this device.

An evaluation of the peer-reviewed scientific literature, including but not limited to subscription materials, has provided Independent Health the basis for its medical necessity coverage outlined above.

Pre-Authorization Required? Yes ☐ No ☒

Pre-authorization is not required at the present time. Criteria above will be utilized upon retro-review.

Definitions

Class II Device is classified by the Food and Drug Administration (FDA) with higher risk than a Class I device and requires greater regulatory controls to provide reasonable assurance of the device's safety and effectiveness. Most medical devices are considered Class II devices. Examples of Class II devices include powered wheelchairs, and some pregnancy test kits. 43% of medical devices fall under this category.

Benign Prostatic Hyperplasia (BPH) is an enlargement or growth of the prostate which restricts the urethra and applies pressure on the base of the bladder. This restriction of the urethra can result in urination difficulties.

Lower Urinary Tract Symptoms (LUTS) include symptoms relating to storage and/or voiding disturbances common among aging men and has been primarily attributed to BPH and consequent bladder outlet obstruction.

Prostatic Urethral Lift (PUL) Urolift implants are permanently placed to lift or hold the enlarged prostate tissue out of the way and increase the opening of the urethra. The permanent Implants are delivered through a small needle that comes out of the UroLift Delivery Device and into the prostate.

References

Related Policies, Processes and Other Documents
N/A

Non-Regulatory references

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Franco, J. V. A., Jung, J. H., Imamura, M. et al. (2022). Minimally invasive treatments for benign prostatic hyperplasia: A cochrane network meta-analysis. BJU International, 130(2), 142-156.

Hayes Inc. Health Technology Assessment. Prostatic Urethral Lift (UroLift System) for Treatment of Symptoms Associated with Benign Prostatic Hyperplasia. Lansdale PA: June 2020.

McVary KT .Surgical treatment of benign prostatic hyperplasia . In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on February 27, 2024).

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Neotract Inc. [web site]. Urolift. Available at: https://www.urolift.com/patients/treatment-options/how-urolift-works.html Accessed February 27, 2024.

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. 2016 Oct;14(5):515-26.

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. 2011;108(1):82-88.

Regulatory References

New York State Department of Health [web site]. New York State Medicaid Program Physician Procedure Codes. Section 5 – Surgery. April 2023. Available at: https://www.emedny.org/ProviderManuals/Physician/PDFS/Physician%20Procedure%20Codes%20Sect5.pdf Accessed February 27, 2024.

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United States Food and Drug Administration (FDA) [website]. Center for Devices and Radiological (CDRH). K193269. Implantable Transprostatic Tissue Retractor System. December 19, 2019. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf19/K193269.pdf Accessed February 27, 2024.

This policy contains medical necessity criteria that apply for this service. Please note that payment for covered services is subject to eligibility criteria, contract exclusions and the limitations noted in the member's contract at the time the services are rendered.

Version Control

Signature / Approval on File? Yes ☒ No☐

Revision Date	Owner	Notes
5/1/2024	Health Care Services	Reviewed
1/1/2024	Health Care Services	Revised
5/1/2023	Health Care Services	Reviewed
5/1/2022	Health Care Services	Reviewed
5/1/2021	Health Care Services	Revised
6/1/2020	Health Care Services	Reviewed
7/1/2019	Medical Management	Revised
8/1/2018	Medical Management	Revised