CLINICAL MEDICAL POLICY	
Policy Name:	Prostatic Urethral Lift
Policy Number:	MP-107-MD-PA
Responsible Department(s):	Medical Management
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Products:	Highmark Wholecare℠ Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 9

Policy History

Date	Activity
03/01/2023	Provider Effective date
01/12/2023	PARP Approval
12/21/2022	QI/UM Committee review
12/21/2022	Annual Review: No changes to clinical criteria. Updated 'Summary of Literature' and 'Reference Sources' sections.
04/01/2022	Provider Effective date
02/07/2022	PARP Approval
12/15/2021	QI/UM Committee review
12/15/2021	Annual Review: No changes to clinical criteria. Updated Summary of Literature and Reference Sources sections.
03/15/2021	Provider Effective Date
02/01/2021	PARP Approval
12/16/2020	QI/UM Committee Review
12/16/2020	Annual Review: updated Summary of Literature & Reference sections. Corrected American Urological Association (AUA) guidance from "< 80mL" to "< 80g".
03/16/2020	Provider effective date
02/05/2020	PARP Approval
12/18/2019	QI/UM Committee review
11/14/2019	Initial policy developed

Disclaimer

Highmark Wholecare ℠ medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

Policy Statement

Highmark Wholecare℠ may provide coverage under the medical-surgical benefits of the Company's Medicaid products for medically necessary prostatic urethral lift (PUL) system for the treatment of symptoms of urinary flow obstruction secondary to benign prostatic hyperplasia (BPH).

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

(Current applicable Pennsylvania HealthChoices Agreement Section V. Program Requirements, B. Prior Authorization of Services, 1. General Prior Authorization Requirements.)

Definitions

Prior Authorization Review Panel (PARP) – A panel of representatives from within the PA Department of Human Services who have been assigned organizational responsibility for the review, approval and denial of all PH-MCO Prior Authorization policies and procedures.

Benign Prostatic Hyperplasia (BPH) - A common condition as men get older. An enlarged prostate gland can cause uncomfortable urinary symptoms, such as blocking the flow of urine out of the bladder. It can also cause bladder, urinary tract, or kidney problems – also referred to as a prostate gland enlargement.

Transurethral Resection of the Prostate (TURP) – A surgical procedure used to treat urinary problems due to an enlarged prostate. A combined visual and surgical instrument (resectoscope) is inserted through the tip of the penis and into the tube that carries urine from the bladder (urethra). The prostate surrounds the urethra. Using the resectoscope, the surgeon trims away excess prostate tissue that is blocking urine flow.

Prostatic Urethral Lift (PUL) System – A minimally invasive system which provides anterolateral mechanical traction of the lateral lobes of the prostate, opening the urethral lumen and reducing urinary obstruction.

Lower Urinary Tract Symptoms (LUTS) – A group of clinical symptoms involving the bladder, urinary sphincter, urethra and, in men, the prostate. Lower urinary tract symptoms are subjectively perceived very differently, so documentation can be taken to record the time and intensity of the voiding to help evaluate the cause of the symptoms.

Procedures

1. The use of the prostatic urethral lift (PUL) (e.g., *UroLift*®) system in patients with moderate-to-severe lower urinary tract obstruction due to benign prostatic hyperplasia (BPH) may be considered medically necessary when ALL of the following patient criteria are met:
    A. Age 45 years or older; AND
    B. The prostate volume is < 80 mL; AND
    C. No obstructive median lobe of the prostate identified on cystoscopy; AND
    D. International Prostate System Score (IPSS) score ≥ 13; AND
    E. Peak flow rate (Qmax) is ≤ 12mL/second; AND
    F. No active urinary tract infection (UTI); AND
    G. No contraindication to, intolerance of, or failure of at least 3 months, of standard medical therapy for BPH (e.g., alpha blocker, PDE5 Inhibitor, finasteride/dutasteride).

2. Contraindications
    The use of the PUL system is contraindicated in patients with ANY of the following conditions:
    - < 45 years of age
    - Prostate volume > 80 mL
    - Obstructive or protruding median lobe of the prostate
    - Current UTI
    - Urethral condition that may prevent insertion of the delivery system into the bladder
    - Urinary incontinence
    - Current gross hematuria
    - Allergy to nickel

3. Post-payment Audit Statement
    The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Wholecare℠ at any time pursuant to the terms of your provider agreement.

4. Place of Service
    The proper place of service for the PUL system is on an outpatient basis.

Governing Bodies Approval

On September 13, 2013, the FDA approved the *UroLift*® system, and it was the first PUL to be approved (NeoTract Inc., Pleasanton, CA). The *UroLift*® system includes a delivery system and a preloaded implant that is performed by an urologist in an outpatient setting. The FDA classified the *UroLift*® System, including both the delivery system and implant, as a Class ll device through the de novo regulatory pathway for novel low-risk medical devices on March 7, 2013. The classification applies to men aged 50 years and older. Subsequent clearances of the *UroLift* System have been made based upon substantial equivalence to the original device. In December 2013, the FDA granted 510(k) clearance for a modified version of the NeoTract *UroLift* system, with the prior version serving as the predicate device. 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 aged 50 years and older.

The FDA expanded approval to include new indications for the existing *UroLift*® devices, including the UL400 and the UL500. The expansion indicated the use in men as young as 45 with an obstructive median lobe. The approval was on February 20, 2018.

Summary of Literature

Benign Prostatic Hyperplasia (BPH) affects approximately 8 million men in the United States, including 30% of men older than 50 years of age and nearly 70% of men older than 70 years of age. BPH restricts the urethra and applies pressure on the base of the bladder and is usually diagnosed by specific clinical features, including an enlarged prostate and mild-to-severe lower urinary tract symptoms (LUTS). Typical categories of LUTS manifestations include storage (irritative) symptoms and voiding symptoms. Storage and voiding symptoms may consist of the following: obstruction, incomplete emptying, intermittency, weak stream, hesitancy, frequency, urgency, and nocturia. A patient's quality of life (QOL) declines due to BPH and can result in erectile dysfunction and depression (Hayes, 2019).

The American Urological Association (AUA) recommends that during the initial evaluation of patients presenting with bothersome LUTS possibly attributed to BPH, clinicians should obtain a medical history, conduct a physical examination, utilize the International Prostate Symptom Score (IPSS), and perform a urinalysis. Patients should be counselled on options for intervention, which can include behavioral/lifestyle modifications, medical therapy and/or referral for discussion of procedural options (AUA, 2021).

Various management options are available for BPH, including symptom monitoring, herbal therapies, surgery, minimally invasive therapies, radiation and medication regimens (Cunningham, 2019). The best treatment choice depends on several factors, including the size of prostate, age, overall health, and the severity of discomfort or pain (Mayo Clinic). The AUA recommends patients should be evaluated by their providers 4-12 weeks after initiating treatment (provided adverse events do not require earlier consultation) to assess response to therapy. Revaluation should include the IPSS. Further evaluation may include a post-void residual (PVR) and uroflowmetry. Patients with bothersome LUTS/BPH who elect initial medical management and do not have symptom improvement and/or experience intolerable side effects should undergo further evaluation and consideration of change in medical management or surgical intervention. (AUA, 2021).

There are a variety of techniques that allow prostatic tissue to be removed (i.e., resected) or destroyed (i.e., ablated), including transurethral resection of the prostate (TURP) and transurethral incision of the prostate (TUIP). There are several other invasive and minimally invasive surgical procedures that are used to treat BPH. Although some of these procedures have improvements in specific urinary symptoms and increased urinary flow, there may be significant complications that result in a decrease in quality of life, depression, and mortality rates. Other complications consist of an increased risk of bleeding, postprostatectomy syndrome, sexual dysfunction, new-onset ejaculatory dysfunction, erectile dysfunction, urethral stricture, and persistent urinary incontinence (Cunningham, 2019).

While different resection and ablation procedures will remain the standard surgical treatments, many patients seek less invasive approaches with minimal risk of complications. The prostatic urethral lift (PUL) procedure is a minimally invasive endoscopic procedure that uses a device (*UroLift*®) to lift and hold the enlarged prostate tissue so it no longer blocks the urethra, thereby increasing the urethral lumen and reducing obstruction to urine flow (Cunningham, 2019). PUL should be considered as a treatment option

for patients with LUTS/BPH provided prostate volume between 30 – 80 cc and verified absence of an obstructive middle lobe. PUL may be offered as a treatment option to eligible patients who desire preservation of erectile and ejaculatory function (AUA, 2021).

PUL alters prostate anatomy without ablating tissue. PUL utilizes transprostatic suture implants delivered by a hand-held device through a cystoscope. The implants are composed of two, T-shaped bars with one on each side of a length of suture. They are spring loaded and deployed with one bar located outside the prostate capsule and the other within the prostatic urethral lumen. The tension between the two bars pulls the lumen of the prostatic urethra towards the capsule, compresses the prostate parenchyma, widens the prostatic urethral lumen, and improves symptoms. If properly placed, the urethral side of the implant epithelializes within 12 months. One of the purported advantages of PUL includes the higher likelihood of preservation of sexual function, demonstrated by the sexual function of men with normal or moderate ED at baseline was unaffected, and those with severe ED reported modest improvement (AUA, 2020).

The Sexual Medicine Society of North America (SMSNA) (2015) issued a letter of communications with medical directors stating that the Society does not consider *UroLift*® to be investigational or experimental, but finds that the device is a standard option for treatment of BPH and that it should be recognized as an appropriate tool.

The American Urological Association (AUA) released updated AUA evidence-based guidelines on Surgical Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia in 2018. AUA issued the following statement:

- Clinicians should consider PUL as an option for patients with LUTS attributed to BPH 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. *(Moderate Recommendation; Evidence Level: Grade C)*
- PUL may be offered to eligible patients concerned with erectile and ejaculatory function for the treatment of LUTS attributed to BPH. *(Conditional Recommendation; Evidence Level: Grade C)*

Guidance from the National Institute for Health and Clinical Excellence (NICE, 2014) states: "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 provided that normal arrangements are in place for clinical governance, consent and audit."

In 2015, NICE published medical technology guidance on the use of the *UroLift*® system for treating lower urinary tract symptoms of benign prostatic hyperplasia. The guidance stated: "the *UroLift*® system should be considered as an alternative to current surgical procedures for use in a day-case setting in individuals with lower urinary tract symptoms of benign prostatic hyperplasia who are aged 50 years and older and who have a prostate of less than 100 mL without an obstructing middle lobe."

Rationale

Roehrborn et al. (2013) reported the first multi-center randomized blinded L.I.F.T. trial of the PUL with *UroLift*® system for the treatment of LUTS secondary to BPH. There were 206 men aged 50 years of age or older with AUASI (American Urological Association Symptom Index) 13 or greater (see *Informational* section below), a maximum flow rate of 12 mL/s or less, and prostate volume 30 cc to 80 cc were randomized. The primary end-point showed an AUASI reduction at three months. The adverse events were typically mild and transient, and there were no occurrences of ejaculatory dysfunction or erectile

dysfunction. The authors concluded that the PUL provided rapid and sustained improvement in symptoms and flow, while preserving sexual function. Roehrborn et al. (2017) reported five-year results of the L.I.F.T study, and the follow-up data showed 13.6% of the patients required surgical retreatment, with 4.3% of the retreated receiving additional PUL implants and 9.3% undergoing TURP or laser ablation. Sustained improvements were reported in symptoms, QOL and urinary flow rate, and an acceptably low surgical retreatment rate of 2%-3% per year.

In addition to the L.I.F.T. trial, there are four other identified clinical studies that studied efficacy and safety of PUL using the *UroLift*® system for symptomatic BPH (Hayes, 2019). The evidence consisted of two RCTs, two prospective pretest/posttest studies, and one retrospective database review. One trial evaluated the comparison of the *UroLift*® system and TURP. The results showed that UroLift® was superior to TURP regarding ejaculatory function and early relief of BPH symptoms (i.e., LUTS). However, improvements in postvoid residual (PVR) volume and peak urinary flow rate were greater among TURP patients rather than *UroLift*® patients. Overall, all trial results suggested a larger rate of BPH symptom relief while maintaining sexual function, and there were significant improvements in QOL. Some studies showed mixed results pertaining to ejaculatory function and uncertainty regarding the comparative effectiveness and safety. There were no reported mortalities, and there were between 6.5% and 20% of *UroLift*® patients that required intervention for LUTS.

A 2020 study sought to show the results of the efficacy of the *UroLift*® system after 7 years of experience. *Urolift*® implants were proposed between February 2012 and March 2019 for patients presenting symptomatic BPH, as an alternative for classic surgery. The efficacy was evaluated with questionnaires about lower urinary tract symptoms (IPSS) and its impact on quality of life (IPSS-QdV). Tolerance was evaluated with questionnaires about erectile (IIEF5) and ejaculatory function (MSHQ-EjD) and complication rate. Survival without additional treatment was assessed using Kaplan-Meier method. Forty patients were treated during this period, with a median follow-up of 32 months. Three months after the procedure, IPSS and IPSS-QdV were significantly improved. MSHQ-EjD and IIEF5 were not modified. Two patients (5%) experienced a urinary retention and needed a bladder catheter. Survival without additional treatment at 5years was 63%. The study concluded that *Urolift*® implants improved significantly the lower urinary tract symptoms in the population, with a good tolerance profile. More than 60% of the patients did not need an additional treatment after 5 years of follow-up (Userovici, et al. 2020).

Hayes, Inc.

- Prostatic Urethral Lift (UroLift System) for Treatment of Symptoms Associated with Benign Prostatic Hyperplasia
    - **C Rating** - For use of prostatic urethral lift with the UroLift System for treatment of lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH). A low-quality body of non-comparative evidence suggests that PUL with the UroLift System may improve LUTS associated with BPH. The effect may be sustained for up to 5 years and is not associated with negative sexual adverse events. Substantial uncertainty remains due to the limited comparative evidence base that trended toward favoring TURP and the limited long-term evidence regarding the durability and safety of this device.

Coding Requirements

Procedure Codes

CPT Code	Description
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)

Diagnosis Codes

ICD-10 Code	Description
N40.1	Benign prostatic hyperplasia with lower urinary tract symptoms, enlarged prostate with lower urinary tract symptoms
N40.3	Nodular prostate with lower urinary tract symptoms
N41.0	Inflammatory diseases of prostate; acute prostatitis
N41.1	Inflammatory diseases of prostate; chronic prostatitis
N41.2	Inflammatory diseases of prostate; abscess of prostate
N41.3	Inflammatory diseases of prostate; prostatocystitis
N41.4	Inflammatory diseases of prostate; granulomatous prostatitis
N41.8	Inflammatory diseases of prostate; other inflammatory diseases of prostate
N41.9	Inflammatory diseases of prostate; inflammatory disease of prostate, unspecified

Informational

Outcome Measurements

Measure	Description
American Urological Association Symptom Index (AUASI)	The AUASI is a 7-item questionnaire on which higher scores indicate more severe symptoms (AUA, 2016).
International Prostate Symptom Score (IPSS)	The IPSS comprises the same 7 questions as the AUASI plus an eighth question addressing health-related QOL). Higher scores indicate more severe symptoms or lower QOL (NICE, 2010).
Peak urinary flow rate (Qmax)	The Qmax is determined with a flowmeter. In general, a urine flow value of < 7 milliliters/second (mL/sec) is considered low and a flow >15 mL/sec is considered normal (Deters et al., 2016).
Postvoid residual (PVR)	The PVR is the quantity of urine remaining in the bladder after urination. It is determined by catheterization or ultrasonography (Deters et al., 2016).
Sexual Health Inventory for Men (SHIM)	The SHIM is equivalent to the IIEF-5, in which lower scores indicate more erectile dysfunction (Cappeleri and Rosen, 2005).
Incontinence Severity Index (ISI)	The ISI consists of 2 questions regarding the frequency and amount of urine leakage. Higher scores indicated more severe incontinence (Sonksen et al., 2015).

Male Sexual Health Questionnaire for Ejaculatory Dysfunction (MSHQ-EjD)	The MSHQ-EjD is a 25-item questionnaire. It has 2 components: a function component, in which lower scores indicate more severe dysfunction; and a bother component, in which higher scores indicate more bother (Rosen et al., 2004).
Benign Prostatic Hyperplasia Impact Index (BPHII)	The 4-item BPHII questionnaire measures the effect of benign prostatic hyperplasia symptoms on everyday life and their interference with daily activities. Higher scores indicate poorer QOL (AUA, 2010).
Short Form 6 Dimension (SF-6D)	The SF-6D 6-item questionnaire measures general health and includes domains for physical functioning, mental health, pain, vitality, social functioning, and role limitations attributable to physical health. Higher scores indicate better health (Gratzke et al., 2017).

Reimbursement

Participating facilities will be reimbursed per their Highmark Wholecare℠ contract.

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