

MEDICAL POLICY		Prostate: Prostatic Urethral Lift	
Effective Date: 7/1/2020		Section: SUR	Policy No: 318
 7/1/2020		Technology Assessment Committee Approved Date: 1/14; 2/15; 2/16	
		Medical Policy Committee Approved Date: 3/17; 5/17; 9/17; 11/18; 12/19; 4/2020	
Medical Officer	Date		

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:

All lines of business

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

POLICY CRITERIA

- I. The prostatic urethral lift (PUL) procedure (i.e. UroLift®) utilizing a maximum of **7** implants may be considered **medically necessary and covered** for the treatment of symptomatic benign prostatic hyperplasia (BPH) when **all** of the following criteria (A.-D.) are met:
 - A. Patient is age 45 or older; **and**
 - B. Patient has moderate-to-severe chronic lower urinary tract symptoms (defined as an American Urologic Association or International Prostate Symptom Score ≥8); **and**
 - C. Pharmacologic BPH treatment has been unsuccessful or intolerable; **and**
 - D. Patient meets **all** of the following indications for the PUL procedure (1.-6.):
 - 1. Has a prostate volume less than 100cc; **and**
 - 2. Does not have an obstructive or protruding median lobe of the prostate; **and**
 - 3. Does not have a urethra condition that may prevent insertion of delivery system into bladder; **and**
 - 4. Does not have an active urinary tract infection (UTI); **and**
 - 5. Does not have current gross hematuria; **and**

6. Urinary incontinence is not due to an incompetent sphincter.

II. The prostatic urethral lift is considered **investigational and not covered** when criterion I. above is not met.

III. Repeat prostatic urethral lift procedures are considered **investigational and are not covered**.

Link to [Policy Summary](#)

CPT/HCPCS CODES

All Lines of Business	
Prior Authorization Required	
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)
C9739	Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants
C9740	Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants

DESCRIPTION

Benign Prostatic Hyperplasia (BPH)

BPH is an enlargement of the prostate gland. The prostate gland sits below the bladder and encircles the urethra (the tube that carries urine out of the body). The prostate naturally grows with age, and as it grows it can begin to compress the urethra and because of this, BPH is very common in aging men. Approximately 50% of all men age 51 to 60 have BPH, and approximately 90% of men over the age of 80 have BPH.¹ Many men with BPH do not have symptoms. Men that do have symptoms usually experience frequent urination, a weak urine stream, and/or leaking urine. These BPH symptoms are commonly referred to as lower urinary tract symptoms (LUTS). The treatment for LUTS usually depends on the severity of symptoms. Men with mild BPH may start with life style changes; while men with moderate-to-severe BPH typically require treatment with medications and possibly surgery.²

Treatment of BPH

Pharmacologic Therapy

There are two types of medicines used to treat BPH: alpha blockers and alpha-reductase inhibitors. Typically, men who start taking BPH medicine will need to take it forever unless surgical treatment is undertaken.² Alpha blockers may be used to treat LUTS related to BPH by relaxing the muscles of the

prostate and bladder neck; thus reducing the pressure on the urethra and more urine flow. Alpha blockers begin to work quickly and are usually recommended as the first-line of treatment for mild-to-moderate BPH symptoms.² Alpha-reductase inhibitors stop the prostate from growing and can even cause it to shrink. This type of medication is recommended for men with larger prostates and can take up to six months for symptom improvement. Common side effects of both BPH medicines include dizziness, loss of libido, and sexual dysfunction. These side effects and the need for life-long BPH medication compliance, lead 30% of men to discontinue their BPH medicine after the first year.³

Transurethral Resection of the Prostate (TURP)

TURP is a surgical treatment for BPH that involves the removal of obstructing tissue from the prostate. In the United States, about 150,000 men have TURPs each year.⁴ The procedure is typically performed under general or spinal anesthesia and requires a 24-48 hour postoperative catheterization observation period. The average recovery time after the TURP procedure is anywhere from 4 to 12 weeks, and patients may also experience a postoperative worsening of LUTS for 4 to 6 weeks. On average, TURP results in a 14.9 International Prostate Symptom Score (IPSS) improvement; therefore making it the gold standard surgical intervention for treatment of BPH.⁵ However, due to the invasive nature of the TURP procedure it is associated with more serious and possibly chronic complications including loss of ejaculatory function (65%), erectile dysfunction (10%), incontinence (3%), excessive bleeding requiring transfusion (2.9%), transurethral resection syndrome (1.4%), and stricture formation (7%).^{5,6} Although the TURP procedure significantly improves LUTS, these potential adverse side effects could considerably impact a patient's quality of life; therefore, new surgical techniques have been proposed as less invasive alternatives to TURP.

Prostatic Urethral Lift (PUL) (UroLift®)

The PUL procedure (i.e. UroLift®) is a surgical treatment for BPH that involves the placement of small mechanical sutures which hold the enlarged prostate tissue out of the way so it no longer blocks the urethra.⁷ This is done by placing small, non-absorbable suture implants with a metallic anchor into the lateral (side) lobes of the prostate. These sutures mechanically separate the lobes in order to help relieve pressure and increase the opening of the urethra. Four to five implants are usually inserted, but this number varies with the size and shape of the prostate.¹⁰ Since the PUL procedure does not remove any obstructing prostate tissue and typically only requires local anesthesia, it is less invasive than other surgical BPH treatments. PUL is typically performed in the doctor's office by an appropriately trained urologist.

REVIEW OF EVIDENCE

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of prostatic urethral lift procedure (PUL) (UroLift®) as a treatment for lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia (BPH). Below is a summary of the available evidence identified through February 2020.

Systematic Reviews

- In 2019, Cochrane published a systematic review evaluating the safety and efficacy of prostatic urethral lift (PUL) for the treatment of lower urinary tract symptoms (LUTS) in patients with benign prostatic hyperplasia (BPH).⁸ Systematically searching the literature through January 2019, investigators identified eligible studies, assessed study quality, extracted data and pooled results. Inclusion criteria were limited to parallel group RCTs. In total, 2 RCTs (n=297) comparing PUL to either sham surgery or TURP were included for review. Outcomes of interest included LUTS scores, quality of life, erectile function, ejaculatory function, adverse events and retreatment rates. The study comparing PUL to sham treatment reported clinically significant improvements in PUL patients' urological symptom scores and quality of life. No significant difference was reported in patients' erectile function or ejaculatory function. Evidence of adverse events was assessed as being of "very low certainty"; no retreatments were reported in either treatment arm at 3-month follow-up. The study comparing PUL to TURP reported outcomes of 91 randomized patients at 12-months follow-up. Investigators concluded that PUL "may result" in substantially less improvement in urological symptom scores relative to TURP, and in comparable or slightly reduced quality of life. Evidence was "very uncertain" regarding whether PUL may cause fewer major adverse events but increased retreatments. At 2-year follow-up, compared to TURP, PUL patients experienced substantially less improvement in urological symptom scores and "little worse to no difference" quality of life scores.

Limitations of studies included lack of blinding in participants and assessors, lack of long-term follow-up and lack of published RCTs more broadly. Due to the paucity of evidence, investigators were unable to perform any of the predefined secondary analyses for either comparator group. Authors concluded that PUL appears to be less effective than TURP in improving urological symptoms at short-term follow-up (i.e. ≤ 2 years). Evidence was uncertain regarding major adverse events, retreatment rates, erectile function and ejaculatory function. Investigators called for additional, higher-quality studies comparing PUL to TURP and other treatment modalities with long-term follow-up.

- In 2019, ECRI published an systematic review⁹ assessing evidence published since their (above-mentioned) 2017 review (discussed below). Investigators limited literature searches to between May 2016 and June 2019. In total, ECRI included 3 studies for review (2 case series, 1 cost-effectiveness study). The first case series reported on international prostate symptom score (IPSS), quality of life, BPH impact index (BPHII) and sexual function among 45 patients with obstructive median lobes at 1-year follow-up.¹⁰ Limitations included the study's small sample size, lack of long-term follow-up, "significant differences"¹⁰ among patients' characteristics at baseline, lack of randomization, blinding and a comparator group. The second case series reported pre- and postprocedure outcomes at 5-year follow-up for 87 patients allocated to the prostatic urethral lift treatment arm of the LIFT study discussed below. The study's validity was limited by its small sample size, but reported 36% superior IPSS improvement compared to patients receiving sham treatment, as well as 61% comparative improvement in quality of life and 70% comparative improvement in BPHII. Investigators concluded that evidence is "somewhat favorable" in support of PUL compared to sham treatment in improving LUTS and quality of life. Nonetheless, authors called for additional RCTs comparing PUL to TURP to further validate findings, assess long-term efficacy, and assess overall efficacy in patients with median lobe obstruction.

- In 2017, ECRI published a health technology assessment of the UroLift® procedure for treating BPH symptoms.¹¹ The authors systematically searched for relevant research published between January 2011 and October 2016 and included three systematic reviews and two randomized controlled trials (RCTs). The evidence suggested that the UroLift® procedure was well-tolerated and works as intended for treating BPH symptoms in most patients for up to three years.¹¹ The ECRI authors also identified the potential benefit of UroLift® for preserving sexual function and quality of recovery compared to TURP. However, 10.7% of UroLift® treated patients experienced treatment failure that required surgical re-intervention. The assessment also noted that 363 UroLift-related complications had occurred across 7 studies, but more than 95% of these complications resolved without medical intervention. Ultimately, the ECRI assessment acknowledged the promising technology of the UroLift procedure, but concluded that future RCTs are needed to confirm the results.
- In 2017 (reviewed 2019), Hayes published a systematic review which included 5 clinical studies (2 RCTs, 2 prospective cohort studies, and 1 retrospective database review) that evaluated the efficacy and safety of the PUL procedure using the UroLift® system for treatment of LUTS related to BPH.¹² The systematic review suggested that PUL was superior to TURP in regards to improvement of the International Prostate Symptom Score (IPSS) and Benign Prostatic Hyperplasia Impact Index (BPHII), early relief of BPH symptoms, and preserving sexual function. However, TURP was reported as superior to UroLift® at improving post-void residual volume (PVR) and peak urinary flow rate (Q_{max}). The included studies reported minor adverse events, such as dysuria (pain when urinating), hematuria (blood in urine), pelvic pain, and urinary tract infections (UTIs). Hayes acknowledged that the UroLift® device does not appear to compromise sexual function and that the adoption of this device, in appropriately selected patients, may reduce the utilization of inpatient hospital services that are required for more invasive procedures; both of which were reported as significant advantages of this device compared to TURP. Hayes considered the studies included in the review to be of low-quality due to small sample sizes, lack of comparison groups (only 1 RCT was a head-to-head comparison), limited follow-up time, and losses to follow-up. Hayes gave an overall “C” rating for use of the UroLift® System as a treatment of LUTS caused by BPH. This rating was based on the low-quality body of evidence noted above and the, “substantial uncertainty that remains due to the dearth of comparative studies and limited long-term evidence regarding the durability and safety of this device.”¹²
- In 2016, Jones et al. conducted a good-quality systematic review to identify, appraise, and synthesize the existing evidence for the UroLift® device to treat LUTS secondary to BPH.¹³ Two independent reviewers conducted a systematic literature search following pre-defined inclusion/exclusion and quality criteria. Ultimately 7 studies (2 RCTs, 1 crossover trial, and 4 cohort studies) were selected for inclusion, with a total of n=440 patients included. The authors divided the outcome measures of the selected studies into two categories: objective (measurable) outcomes and subjective (opinion based) outcomes. The objective outcome measures included prostate-specific antigen (PSA), post-void residual (PVR) volume, and maximum urinary flow rate (Q_{max}). The subjective outcome measures included in the systematic review were the International Prostate Symptom Score (IPSS), Quality of Life (QoL), International Index of Erectile Function (IIEF), and Sexual Health Inventory for Men (SHIM).

The UroLift® procedure exhibited improvements in both objective and subjective outcome measures; however, the most significant improvements were in the subjective measures. Unlike TURP, the UroLift® did not demonstrate significant, long-term improvements in PVR and Q_{max} . The

authors suggested that studies with longer follow-up periods were needed to confirm its durability and long-term efficacy. The review also evaluated the UroLift® safety profile in the selected studies. Authors reported the UroLift had favorable advantage over TURP in the ability to preserve sexual function. The authors also recognized that careful patient selection was vital when choosing to perform UroLift, given all the explicit indications for the procedure, and that the efficacy and safety had yet to be proven among men with more complicated health problems.

There were several strengths of this systematic review, including the selection of high quality studies which were published within the last 5 years and the systematic approach taken for selecting literature and extracting data. Limitations of this systematic review were due to the limited number of quality studies on the UroLift® procedure and the inability to conduct a meta-analysis because the selected studies varied in type and quality. Ultimately, the authors concluded that the UroLift® procedure, “may not be an end-of-the-line intervention but rather, an intermediate, minimally invasive option for a specific population of men who wish to preserve sexual function as a key priority in their treatment.”¹³

Randomized Controlled Trials (RCTs)

- The L.I.F.T. study (Luminal Improvement Following Prostatic Tissue Approximation for the Treatment of LUTS secondary to BPH) was a prospective, randomized, controlled, blinded study conducted across 19 centers in the United States, Canada, and Australia.¹⁴ Participants were eligible for inclusion under the following criteria:
 1. >50 years old
 2. IPSS ≥ 13
 3. Peak flow (Q_{max}) ≤ 12 mL/s
 4. Prostate volume 30-80cc
 5. Absence of obstructive median lobe
 6. Absence of active UTI

A total of 206 participants were enrolled and randomized 2:1 into the treatment (PUL) and sham groups (PUL=140, sham=66). Blinding was done by placement of a surgical screen to block the patient’s view and the outcome assessment was completed by someone who was not involved in the original procedure. The sham procedure involved rigid cystoscopy (a procedure to check for any problems in the bladder) with simulated active treatment sounds. PUL participants received anywhere from 2-11 implants. The outcomes of interest were IPSS, QoL, BPH Impact Index, Q_{max} , sexual function, and adverse events. After the 3 month follow-up, the sham patients were unblinded and offered enrollment into a crossover study where they would receive PUL treatment and be followed for 24 months (Rukstalis et al. study described below).

The L.I.F.T. RCT is now reporting results on effectiveness, safety, and durability from their 5 year follow-up. The effectiveness of the PUL procedure in regards to IPSS, QoL, BPH Impact Index, and Q_{max} has been sustained through 5 years. The most significant adverse event reported was encrustation of the implant(s) caused by urine exposure when placed too close to the bladder. Of the 642 implants placed during the L.I.F.T. study, 14 implants (2%) in 10 subjects were encrusted and had to be removed. Other reported adverse events were mild-to-moderate and resolved within 2-4 weeks without treatment. In regards to durability of the UroLift® procedure, 13.6% of the 140

originally enrolled subjects required surgical retreatment. Conversely, additional LUTS treatment after TURP is estimated to be about 6% at 2 years and 8% at 5 years.¹⁵ Sexual function was also evaluated in the L.I.F.T. patients. There were no reports of sexual dysfunction (erectile dysfunction and ejaculatory dysfunction) following the PUL procedure. Also, all patients were able to undergo the procedure under local anesthesia in the urologist's office. The authors attempted to standardize the number of required implants by evaluating prostate size and number of implants placed, but no correlation was found.

The methodological strengths of this study included recruitment from 19 different health centers across 3 countries, a large sample size based on a power calculation, randomized design, blinding, and comparison to a sham procedure. Analysis was also conducted using the intention-to-treat methodology and patients that experienced protocol deviations or had other prostate-related treatments were censored out of the analysis. Limitations of the L.I.F.T. RCT include the subjective nature of 4 of the 6 outcomes of interest, short follow-up of the sham group (3 months), significant losses to follow-up by year 4, and no comparison to a standard of care surgical BPH treatment (i.e. TURP).

- Gratzke et al. conducted a prospective, multi-center, randomized study to compare PUL to TURP for the treatment of LUTS secondary to BPH.¹⁵ Currently, this is the only head-to-head comparison of PUL using the UroLift® device with the gold standard TURP procedure. Subject eligibility was based on the following criteria:
 1. ≥ 50 years old
 2. IPSS > 12
 3. $Q_{max} \leq 15$ mL/s
 4. Prostate volume ≤ 60 cc per ultrasound.

A total of n=80 participants were recruited from 10 different European health centers, randomized 1:1, and followed for 2 years. The primary study endpoint, the BPH6 questionnaire, was specifically designed for this RCT. The BPH6 is a composite of the following 6 other validated questionnaires which assesses overall health:

1. International Prostate Symptom Score (IPSS)
2. Sexual Health Inventory for Men (SHIM)
3. Male Sexual Health Questionnaire for Ejaculatory Dysfunction (MSHQ-EjD)
4. Incontinence Severity Index
5. Quality of Recovery Visual Analog Score
6. Clavien-Dindo classification of adverse events (AEs)

Secondary endpoints were measures of patient satisfaction, quality of life (QoL), BPH Impact Index, peak flow rate (Q_{max}), and sleep disturbances.

Significant improvements were seen in both groups; however, TURP was superior to PUL for improvements in IPSS and Q_{max} , while PUL was superior to TURP for QoL, quality of recovery, and postoperative sexual function. At the 2 year follow-up, 100% of PUL patients had preserved sexual function while 34% of TURP patients reported ejaculatory dysfunction. TURP patients also experienced a statistically significant worsening of continence function at the 2 week and 3 month

follow-up (> 1 point change from baseline for the incontinence severity index (ISI) score) while the PUL patients maintained baseline continence throughout the 2 year follow-up. In regards to 2 year durability of PUL versus TURP, 6 PUL patients (13.6%) and 2 TURP patients (5.7%) required secondary treatment for return of LUTS during the follow-up period.

Strengths of this RCT included its randomized, controlled design and recruitment from 10 different health centers across Europe. Limitations are due to the small sample size, short follow-up period, and lack of blinding. A significant limitation of this RCT was the use of the BPH6 questionnaire as the primary endpoint. Although the authors stated the questionnaire is based on validated questionnaires, the BPH6 itself has yet to be validated. Using this questionnaire as the primary endpoint of the RCT creates a significant amount of doubt as to the reliability and validity of these results.

Nonrandomized Studies

- Rukstalis et al. evaluated the 2 year effectiveness and durability of PUL in a cross over study of the L.I.F.T. RCT sham patients.¹⁶ Participants were eligible for inclusion under the criteria as the original L.I.F.T. RCT.

A total of 51 patients were enrolled in the crossover study, underwent the PUL procedure, and were followed-up through 24 months. The selected outcomes of interest were IPSS, Q_{max} , QoL, and BPH Impact Index. The PUL procedure was efficacious for all outcomes through 24 months. Also, sexual function was preserved in all patients with no reported incidences of erectile or ejaculatory dysfunction. The reported adverse events were mild-to-moderate and typically resolved within 2 weeks. Of the 241 devices implanted in the cross over patients, 10 devices (4%) were found to have encrustation due to improper placement and required removal. Also of note, 4 patients (8%) progressed to TURP and 1 patient (2%) required additional PUL implants. Methodological strengths of this study included recruitment out of 19 health centers across 3 countries and the randomized design (from the L.I.F.T. RCT). Limitations included the small sample size and short follow-up period. There were 15 losses to follow-up and no comparison to the gold standard surgical BPH treatment. Also, bias of the results is probable because 3 of the 4 outcome measures were subjective.

- Sievert et al. (2018) evaluated the 2 year effectiveness of Urolift among 86 patients electing the procedure instead of transurethral resection of the prostate (TURP).

At 2 years, 86% (n=74) of patients reported statistically significant improvement in symptoms, flow and quality of life. Some patients, 12.8% (n=11), reported persistence of LUTS or remaining PVR, only two of whom elected more implants, one of whom improved while the other did not. Adverse effects were minimal. Limitations include the relatively short follow-up period (2 years); very poor response rate at follow up (47%) and non-randomized study design. Inclusion criteria were also broader than most North American studies, with no exclusions made on the basis of high post-void residual volume (PVR), prostate size, retention history or LUTS oral therapy.¹⁷

- Walsh (2017) gave an overview of advanced surgical techniques for PUL surgery. Walsh noted that, “while four implants are sufficient for many prostates, there are particular anatomical variations that require additional implants. Long prostatic urethras may require three implants along the

length of each lateral lobe. Patients with a high bladder neck, a modest non-obstructing median lobe or protruding anterior tissue may benefit from supplemental implant(s) near the bladder neck.”¹⁸

In a narrative review of five recent PUL clinical studies (n=44-137), Roehrborn (2016), lead investigator of the LIFT study, noted that the average number of implants patients receive ranges from 3.7 to 4.9.¹⁹

Repeat Prostatic Urethral Lift Procedures

No studies were identified addressing the safety or efficacy of repeat prostatic urethral lift procedures.

CLINICAL PRACTICE GUIDELINES

American Urological Association (AUA)

In 2019, the AUA published an evidence-based clinical practice guideline addressing the surgical management of lower urinary tract symptoms attributed to benign prostatic hyperplasia.²⁰ On the basis of grade “C” level evidence, authors issued a “moderate recommendation” supporting the use of prostatic urethral lift in patients with LUTS/BPH, a prostate of less than 80g and the verified absence of an obstructive middle lobe. Authors reviewed the Rukstalis et al. study¹⁰ because of which the FDA expanded indications to allow for patients with an obstructive median lobe. Investigators nonetheless ultimately excluded the study on the grounds that it was “essentially a case series with pre-post outcomes.”²⁰ Authors also recommended that PUL patients be informed that symptom reduction and flow rate improvement is less significant compared to TURP, and that evidence of efficacy and retreatment rates remain “poorly defined.”²⁰

A “conditional recommendation” was made for PUL in patients concerned with erectile and ejaculatory function for the treatment of LUTS/BPH.

Health Evidence Review Commission (HERC) Oregon

In 2018, HERC published a coverage guidance addressing prostatic urethral lift for the treatment of benign prostatic hypertrophy.²¹ On the basis of three studies, investigators issued a “strong recommendation” in support of PUL for the treatment of patients with symptomatic BPH when the following criteria are met:

- Age 50 or older
- Estimated prostate volume <80cc
- IPSS score ≥ 13
- No obstructive median lobe of the prostate identified on cystoscopy at the time of the procedure
- Failure, contraindication, or intolerance to at least three months of conventional medication therapy for benign prostatic hypertrophy

Sexual Medicine Society of North America (SMSNA)

In 2017, the SMSNA released a position statement indicating support for the UroLift® procedure as a treatment of LUTS secondary to BPH. Although this is not an evidence-based clinical practice guideline, authors recognized UroLift® as a treatment option for men with symptomatic BPH due to the available evidence supporting its, “favorable sexual side effect profile over alternative therapies.”²²

National Institute for Health and Care Excellence (NICE)

In 2015, NICE recommend the use of the UroLift® system for treating lower urinary tract symptoms caused by benign prostatic hyperplasia. Investigators recommend the UroLift® system be, “considered an alternative to current surgical procedures for use in a day-case setting in men with lower urinary tract symptoms of benign prostatic hyperplasia who are aged 50 years and older and who have a prostate less than 100 mL without an obstructing middle lobe.”²³

CENTERS FOR MEDICARE & MEDICAID

As of February 2020, no Centers for Medicare & Medicaid (CMS) coverage guidance was identified which addresses prostatic urethral lift as a treatment of BPH.

POLICY SUMMARY

Although current evidence does not support the durability or efficacy of PUL compared to TURP, PUL appears to have significant advantages over TURP due to the less invasive and more convenient nature of the procedure. One of the most notable advantages of the PUL procedure is its ability to significantly preserve sexual and continence function compared to TURP. Additionally, several high-quality clinical practice guidelines conditionally recommend PUL for select patients. Due to the limited number of RCTs comparing PUL to TURP, PUL should not be seen as a replacement for TURP, but rather as an intermediate, minimally invasive option which may prolong the time to a more invasive surgical treatment. While patients typically require 4 implants, patient anatomy varies and some individuals may require additional implants to durably ensure prostatic de-obstruction. Long-term, high quality prospective studies are needed to confirm the long-term efficacy of the PUL procedure as a treatment for LUTS related to BPH. Studies evaluating the long-term benefit and durability of repeat UroLift procedures are also lacking.

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

U.S. Food and Drug Administration (FDA)

The UroLift System (NeoTract Inc.) received clearance as a class II device through the *de novo* regulatory pathway for novel, low-risk medical devices in March 2013.²⁴ Subsequent clearances have been made based on substantial equivalence to the original device. Indications were expanded to include obstructive lateral and median lobes in December 2017,²⁵ and prostates with volumes of less than 100cc in December 2019.²⁶

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

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