Subject: Prostatic Urethral Lift or UroLift for Benign Prostatic Hyperplasia (BPH)		Original Effective Date: 6/2/2015
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DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina Clinical Policy (MCP) document and provide the directive for all Medicare members.[1]

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DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

The prostatic urethral lift (PUL) or UroLift System is a minimally invasive technology for treating lower urinary tract symptoms due to benign prostatic hyperplasia (BPH). The UroLift is a permanent implant that is inserted during a minimally invasive transurethral outpatient procedure proposed to relieve prostate obstruction and open the urethra directly leaving the prostate intact. The PUL procedure consists of small permanent transprostatic implants placed cystoscopically to compress the prostate tissue, therefore increasing the urethral lumen and reducing obstruction to urine flow. Subsequently, 4 or 5 implants are delivered into the prostatic urethra to maintain urethral patency. A final cystoscopy confirms that the implants were appropriately

positioned. Most common adverse events reported include hematuria, dysuria, micturition urgency, pelvic pain, and urge incontinence.

On September 13, 2013, the FDA approved the UroLift for marketing through a de novo classification as a class II device used as a permanent implant to relieve low or blocked urine flow in men aged 50 and older with BPH. According to the FDA The UroLift® System should not be used if the patient has any of the following conditions: [2]

- Prostate volume of >80 cc
- An obstructive or protruding median lobe of the prostate
- A urinary tract infection
- Urethra conditions that may prevent insertion of delivery system into bladder
- Urinary incontinence
- Current gross hematuria
- A known allergy to nickel

RECOMMENDATION

The prostatic urethral lift or UroLift for individuals with symptomatic Benign Prostatic Hyperplasia (BPH) may be considered medically necessary when all of the following criteria are met: [ALL]

- ❑ Age ≥ 50 years; and
- ❑ Diagnosis of moderate to severe BPH defined as:
    - American Urological Association (AUA) symptom score above 7 with signs of obstruction that include:
        - ➢ increased voiding symptoms; or
        - ➢ decreased peak urinary flow rate (i.e. a peak urine flow rate (Qmax) less than 15 cc/sec on a voided volume that is greater than 125 cc); and
- ❑ Refractory to or intolerant of standard BPH medication; and
- ❑ Enlarged lateral lobes without an obstructive median lobe; and
- ❑ Prostatic volume less than or equal to 80 cc; and
- ❑ No active urinary infection; and
- ❑ Normal renal function; and
- ❑ No allergy to nickel

SUMMARY OF MEDICAL EVIDENCE [3-18]

There is sufficient published evidence to assess the role of the Prostatic urethral lift (PUL) or UroLift for the treatment of patients with for benign prostatic hyperplasia. The Prostatic Urethral Lift or UroLift is described as a minimally invasive alternative to drug therapy and/or surgery and may be a viable alternative for men who require surgical therapy for BPH due to medically refractory symptoms.

A summary of the most relevant studies are outlined below.

The best available published evidence is the randomized sham-controlled FDA pivotal LIFT trial [11] reported by Roehrborn et al. (2013) of a PUL device for treatment of lower urinary tract symptoms (LUTS) secondary to BPH. The patient and questionnaire administrator were blinded to the randomization. Men aged > 50 years with

an American Urological Association Symptom Index (AUASI) of > 13, a maximum flow rate of 12 ml/second or less, and a prostate of 30 to 80 cc were randomized 2:1 to PUL or sham. The sham consisted of rigid cystoscopy with sounds mimicking those heard with the PUL placement. At three months, the AUASI reduction was assessed; the primary end point of the study was to have an AUASI reduction of 25% greater than the sham. The PUL subjects were also assessed at one year for LUTS, peak urinary flow rate, quality of life and sexual function. Altogether, 206 men were randomized (140 to PUL, 66 to sham). Patients were evaluated at 1, 3, 6, and 12 months. The PUL patients had an AUASI reduction of 11.1 + 7.67 whereas the sham patients change was 5.9 + 7.66 (P = 0.003) at three months. The PUL reduction remained at 12 months. Peak urinary flow was increased 4.4 ml at 3 months and remained at 4.0 ml/second at 12 months (p <0.001). There was no new ejaculatory or erectile dysfunction. Adverse events were described as mild and transient. There was a 5% retreatment rate at one year. A follow up to this study by Roehrborn et al. (2015) reported that at 2 years, 106 men treated with the UroLift were evaluable for the per-protocol analysis. In these patients, the AUASI score (−9.2 ± 7.57), QOL (−2.2 ± 1.71), and Qmax (mean 4.2 mL per second) remained improved by 42%, 48%, and 58%, respectively (P<0.0001 for all). The reduction in the BPHII score was also sustained compared with baseline (−55.6 ± 3.4) (P<0.0001).[12] Three year results of the same LIFT 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.[13]

As a follow-up to the LIFT trial, Roehrborn et al. (2017) reported the five year results of a prospective, multi-center, randomized, blinded sham control trial of the Prostatic Urethral Lift (PUL) in men with bothersome lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH). At 19 centers in North America and Australia, 206 subjects ≥ 50 years old with International Prostate Symptom Score (IPSS) > 12, peak flow rate (Qmax) ≤ 12 mL/s, and prostate volume 30 cc-80 cc were randomized 2:1 to the PUL procedure or blinded sham control. In PUL permanent UroLift implants are placed to hold open the lateral lobes of the prostate to reduce urinary obstruction. After randomized comparison at 3 months and the only opportunity to add more PUL implants, PUL patients were followed to 5 years. LUTS severity (IPSS), quality of life (QOL), BPH Impact Index (BPHII), Qmax, sexual function, and adverse events were assessed throughout follow up. IPSS improvement after PUL was 88% greater than that of sham at 3 months. LUTS and QOL were significantly improved by 2 weeks with return to preoperative physical activity within 8.6 days. Improvement in IPSS, QOL, BPHII, and Qmax were durable through 5 years with improvements of 36%, 50%, 52%, and 44% respectively. No difference was seen between Intent to Treat and Per Protocol populations. Surgical retreatment was 13.6% over 5 years. Adverse events were mild to moderate and transient. Sexual function was stable over 5 years with no de novo, sustained erectile or ejaculatory dysfunction. [14]

McVary et al. (2013) analyzed the sexual function of the men in the Roehrborn et al. study immediately above. Men ≥50 years with prostates 30-80 cc, International Prostate Symptom Score (IPSS) >12, and peak urinary flow rate (Qmax) ≤12 ml/s were randomized 2:1 between PUL and sham. Blinded groups were compared at 3 months and active arm then followed to 12 months for LUTS with IPSS and for sexual function with sexual health inventory for men (SHIM) and Male Sexual Health Questionnaire for Ejaculatory Dysfunction (MSHQ-EjD). No evidence of degradation in erectile or ejaculatory function after PUL was found. SHIM and MSHQ-EjD scores were not different from control at 3 months but were modestly improved and statistically different from baseline at 1 year. [9]

McNicholas et al. (2013) described the outcomes of 102 men with symptomatic BPH treated at seven centers in five countries. The study was had a single arm and was not blinded. Average age was 68 years, average prostate size was 48 cm3, and average IPPS was 23. Patients were followed at 2 and 6 weeks, and 3, 6, and 12 months postoperatively. The mean IPPS improved 36%, the mean QOL improved 39%, and the maximum flow rate (Qmax) improved by 38% by two weeks. At 12 months observation, these rates of improvement were 52%, 53% and 51% respectively. These results were statistically significant although the postvoid residual volume (PVR) did not show a statistically significant change. There were no reports of retrograde ejaculation. Transurethral resection of the prostate (TURP) occurred in four patients (6.5%). Adverse events were short duration of dysuria (25%), hematuria (16%), and urgency (10%). [8]

Cantwell et al. (2014) conducted a prospective crossover trial of PUL in patients with LUTS due to BPH. Men > 50 years old with an IPPS > 13, a Qmax of <12 mL/s, and a prostate of 30-80 mL were enrolled. The study was prospective, randomized, controlled, "blinded," and conducted in 19 centers in the USA, Canada, and Australia. Patients underwent a sham procedure with rigid cystoscopy, inability to see the operator or endoscopy imaging, and hearing sounds associated with an operative procedure. Three to six months later the patients were re-assessed and a PUL was placed. At entry, there were 66 men; 53 (80%) elected to have the PUL. There was a similar change in the IPPS for both sham and crossover PUL patients at two weeks, but the change continued to increase in the latter group and reached statistical significance at three months. In contrast, the urinary flow rate change was more durable three months after the sham rigid cystoscopy showing a 2.4 mL/s increase in Qmax at 3 months. There was further improvement at 3 months post-PUL which was maintained at 12 months. Improvements in IPPS 3 months post-PUL was 11.1 points or 122% greater than the 3 month post-sham improvement of 5.0 points ($P < 0.001$). Improvements were similar to those noted in the study by Roehrborn et al. (2013) described above. Clinically and statistically significant improvement in Health Related Quality of Life (HRQL) scores and BPHII post-PUL also occurred. Sexual function was maintained. Adverse events were primarily mild except for two patients who developed urinary retention. One patient progressed to TURP. [3]

Chin et al. (2012) evaluated a prostatic urethral lift (PUL) device placed in 64 men, > 55 years old, with moderate to severe symptomatic benign prostatic hyperplasia treated in six (6) Australian facilities. Effectiveness was evaluated at 2 weeks and 3, 6, 12, and 24 months. The International Prostate Symptom Score (IPPS) decreased 42% in 2 weeks, 49% at 6 months, and 42% at two years. Patients treated early in the study had a 34% decrease at three years. The quality of life score (QOL) score improved from an average of 4.9 at baseline to 2.7 at 2 weeks, and 2.5 at one and two years. The BPH Impact Index (BPHII) decreased 39% at 2 weeks with a 60% reduction at 2 years; these results were statistically significant at each measurement period. Peak flow increased an average amount of > 30% at all intervals. There were no findings of degraded erectile function. Numbers of evaluable patients were not clear although it was noted that the sample size was reduced at 24 months because not all of the patients had reached that point of follow-up. There was no active or sham control group. Twenty percent (20%) (13/64) of the initially treated patients required repeat treatment. [4]

Professional Society Guidelines

The National Institute for Health and Clinical Excellence (NICE, 2015) indicates that the 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. [20]

CODING INFORMATION THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

CPT	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)

HCPCS	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	Description: [For dates of service on or after 10/01/2015]
N40.0-N40.3	Enlarged prostate range of codes

REFERENCES

Government Agency

1. Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database. Advanced Search: National Coverage Documents [search:]. Available at: http://www.cms.gov/medicare-coverage-database/
2. Food and Drug Administration [website]. De novo Classification Request for Neotract's Urolift System. March 7, 2013Accessed at: http://www.accessdata.fda.gov/cdrh_docs/reviews/K130651.pdf

Peer Reviewed Publications

3. Cantwell AL, Bogache WK, Richardson SF, Tutrone RF, Barkin J, Fagelson JE, Chin PT, Woo HH. 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 Apr;113(4):615-22. doi: 10.1111/bju.12540.
4. Chin PT, Bolton DM, Jack G, Rashid P et al. Prostatic urethral lift: two-year results after treatment for lower urinary tract symptoms secondary to benign prostatic hyperplasia. Urology. 2012 Jan;79(1):5-11. doi: 10.1016/j.urology.2011.10.021.
5. 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 Int. 2017;119(5):767-775.

6. Gravas S, Bach T, Bachmann A, et al. Treatment of Non-neurogenic Male LUTS. 2017. European Association of Urology [website]. Accessed at: https://uroweb.org/guideline/treatment-of-non-neurogenic-male-luts/.
7. Larcher A1, Broglia L, Lughezzani G. Urethral lift for benign prostatic hyperplasia: a comprehensive review of the literature. Curr Urol Rep. 2013 Dec;14(6):620-7. doi: 10.1007/s11934-013-0348-3.
8. McNicholas TA1, Woo HH, Chin PT et al. Minimally invasive prostatic urethral lift: surgical technique and multinational experience. Eur Urol. 2013 Aug;64(2):292-9. doi: 10.1016/j.eururo.2013.01.008. Epub 2013 Jan 19.
9. McVary KT1, 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. doi: 10.1111/jsm.12333. Epub 2013 Sep 30.
10. Perera M1, Roberts MJ2, Doi SA3, Bolton D4Prostatic 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. 2014 Nov 15. pii: S0302-2838(14)01120-8. doi: 10.1016/j.eururo.2014.10.031. [Epub ahead of print]
11. Roehrborn CG1, 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. doi: 10.1016/j.juro.2013.05.116. Epub 2013 Jun 11.
12. Roehrborn CG, Gange SN, Shore ND, et al. Durability of the prostatic urethral lift: 2-year results of the L.I.F.T. study. Urol Pract. 2015;2:26-32.
13. 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.
14. Roehrborn CG, Barkin J, Gange SN, et al. Five year results of the prospective randomized controlled prostatic urethral L.I.F.T. Study. Can J Urol. 2017;24(3):8802-8813.
15. Rukstalis D, Rashid P, Bogache WK, et al. 24-month durability after crossover to the prostatic urethral lift from randomised, blinded sham. BJU Int. 2016;118(Suppl 3):14-22.
16. Sánchez-Gómez LM1, Polo-deSantos M2, Gómez-Sancha F3, Luengo-Matos S2. Efficacy and Safety of the Urolift® System for the Treatment of Benign Prostate Hyperplasia Symptoms: Systematic Review. Actas Urol Esp. 2014 Sep 23. pii: S0210-4806(14)00203-4. doi: 10.1016/j.acuro.2014.05.010. [Epub ahead of print]
17. Sonksen 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;68(4):643-652.
18. Woo HH1, Bolton DM, Laborde E et al. Preservation of sexual function with the prostatic urethral lift: a novel treatment for lower urinary tract symptoms secondary to benign prostatic hyperplasia. J Sex Med. 2012 Feb;9(2):568-75. doi: 10.1111/j.1743-6109.2011.02568.x. Epub 2011 Dec 16.

Professional Organization Guidelines

19. American Urological Association (AUA) Practice Guidelines Committee (2010, reviewed last 2014) AUA guideline on management of benign prostatic hyperplasia. Guideline on the management of benign prostatic hyperplasia (BPH). Available at: https://www.auanet.org/education/guidelines/benign-prostatic-hyperplasia.cfm

20. National Institute for Health and Care Excellence (NICE). UroLift for treating lower urinary tract symptoms of benign prostatic hyperplasia. London, UK: National Institute for Health and Care Excellence; 2015. NICE Medical Technology Guidance No. 26. 2019: Under re-review 2020. Accessed at: https://www.nice.org.uk/guidance/mtg26.
21. Hayes a Tract Manager Company. Winifred Hayes Inc. Lansdale, Pa.
    - Prognosis Report. UroLift System. Oct 2013. Archived 2014.
    - HTA: UroLift System (NeoTract Inc.) for Treatment of Benign Prostatic Hypertrophy. Nov, 2017 and updated Aug, 2020.

Other Resources

22. UpToDate: [website]: Waltham, MA. Walters Kluwer Health; 2020.
    - Cunningham G, Kadmon D. Transurethral procedures for treating benign prostatic hyperplasia.
23. Peer Review: Policy reviewed by AMR practicing physician board certified in Urology, 1/8/18.

Revision/Review History:

6/2/15: New Policy
12/16/2015, 12/14/2016 & 6/22/2017: Policy reviewed, no changes.
3/8/18: This policy was reviewed and updated from investigational status to medically necessary criteria based on newly published evidence. Summary of medical evidence, professional guidelines and reference sections were updated.
9/18/19 & 9/16/20: Policy reviewed, no changes. Updated references, added TOC.