

UROLIFT / PROSTATIC URETHRAL LIFT

Effective Date: October 1, 2015
Date Of Origin: August 12, 2015

Review Dates: 8/15, 8/16, 8/17, 8/18, 11/18
Status: Current

Summary of Changes

Modifications:

- Qualifying minimum age was reduced from 50 years to 45 years.

I. POLICY/CRITERIA

- A. The Urolift/Prostatic Urethral Lift System is a covered benefit for the treatment of symptomatic benign prostatic hypertrophy (BPH) when **both** of the following are met:
1. Men age 45 and older, and
 2. Prostate up to 80 cc

Coverage is limited to a maximum of seven (7) implants.

- B. Urolift is not a covered benefit if *any* of the following are present:
1. Obstructive median lobe
 2. Urinary retention
 3. Post-void residual volume greater than 250 ml
 4. Active infection
 5. Gross hematuria
 6. Cystolithiasis within 3 months
 7. Prostate specific antigen greater than 10 ng/ml (unless biopsy was negative)
 8. Bacterial prostatitis within 1 year

II. MEDICAL NECESSITY REVIEW

Required Not Required Not Applicable

III. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- ❖ **HMO/EPO:** *This policy applies to insured HMO/EPO plans.*
- ❖ **POS:** *This policy applies to insured POS plans.*

- ❖ **PPO:** *This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.*
- ❖ **ASO:** *For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.*
- ❖ **INDIVIDUAL:** *For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.*
- ❖ **MEDICARE:** *Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.*
- ❖ **MEDICAID/HEALTHY MICHIGAN PLAN:** *For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.*

IV. BACKGROUND

The UroLift System (NeoTract Inc.) is a minimally invasive, prostatic urethral lift (PUL) system that provides anterolateral mechanical traction of the lateral lobes of the prostate, opening the urethral lumen and reducing obstruction. Implants are delivered bilaterally to separate the encroaching lobes, beginning approximately 1.5 centimeters distal to the bladder neck. Cystoscopic inspection after each implant determines whether additional implants are required. Four to 5 implants are typically placed but this varies with the size and shape of the prostate. The device may avoid some of the morbidities and complications associated with other surgical approaches.

The UroLift System is intended for the treatment of symptoms due to urinary outflow obstruction secondary to BPH in men ≥ 50 years of age with a prostate size up to 80 milliliters (mL) in size whose symptoms are refractory to medical therapy, and/or who are inappropriate candidates for more invasive procedures or who do not wish to undergo these procedures. The procedure is typically performed by a urologist in the office or other outpatient setting with the use of local anesthesia and oral sedation.

The L.I.F.T. Study randomized 206 patients with BPH to implantation of the UroLift device versus a sham procedure and met its primary endpoint finding that patients treated with the device had a $\geq 25\%$ reduction in the American Urological Association Symptom Index (AUASI) ($P < 0.0001$) at 3 months compared with the

sham controls, which was sustained at 1 year. Other endpoints that were improved at 3 months and at 1 year in the UroLift group compared with the controls included the Benign Prostatic Hyperplasia Impact Index (BPHII) ($P < 0.001$ for both time points) and maximum urinary flow rate (Q_{max}) ($P < 0.0001$ for both time points). Changes in scores on the Male Sexual Health Questionnaire for Ejaculatory Dysfunction (MSHQ-EjD), MSHQ-bother, and International Index of Erectile Function (IIEF-5) were similar between the UroLift group and the controls at 3 months and at 1 year. These clinical benefits were sustained through 2 years as shown by follow-up of 106 patients available for analysis.

V. CODING INFORMATION

ICD-10 Codes that *may* apply:

N40.1 Enlarged prostate with lower urinary tract symptoms

CPT/HCPCS Codes:

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)

Outpatient Facility Codes:

C9739 Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants

C9740 Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants

L8699 Prosthetic implant, not otherwise specified

VI. REFERENCES

1. Hayes, Inc. UroLift System (NeoTract Inc.) for Treatment of Benign Prostatic Hypertrophy, April 23, 2015
2. Benign Prostatic Hypertrophy Treatments, Aetna Clinical Policy Bulletin @ http://www.aetna.com/cpb/medical/data/1_99/0079.html (Retrieved July 22, 2015, June 30, 2016, July 3, 2017 & June 6, 2018)
3. Roehrborn, C. G., Gange, S. N., et.al. Durability of the prostatic urethral lift: 2-year results of the L.I.F.T. Study. Urology Practice Journal, 16 September 2014
4. Benign Prostatic Hyperplasia (BPH) Treatments. Cigna Medical Coverage Policy 0159. https://cignaforhcp.cigna.com/public/content/pdf/coveragePolicies/medical/mm_0159_coveragepositioncriteria_benign_prostatic_hypertrophy_trtmt_svc.pdf (Retrieved July 3, 2017 & June 6, 2018).

5. Prostatic Urethral Lift Procedure for the Treatment of BPH. Blue Cross Blue Shield Blue Care Network of Michigan Joint Medical Policy. https://cignaforhcp.cigna.com/public/content/pdf/coveragePolicies/medical/mm_0159_coveragepositioncriteria_benign_prostatic_hypertrophy_trtmt_svc.pdf (Retrieved July 3, 2017).
6. Foster HE, et al. Surgical Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: American Urological Association (AUA) Guideline. May 2018.

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