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Original Effective Date: 03/15/05

Reviewed: 09/26/24

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Subject: Temporary Prostatic Urethral Stents (Including Implantable Nitinol Devices) and Prostatic Urethral Lift

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Benign prostatic hyperplasia (BPH) is a common disorder among older individuals that results from hyperplastic nodules in the periurethral or transitional zone of the prostate. The clinical manifestations of BPH include increased urinary frequency, nocturia, urgency or hesitancy to urinate, and a weak stream when urinating. The urinary tract symptoms often progress with worsening hypertrophy and may lead to acute urinary retention, incontinence, renal insufficiency, and/or urinary tract infection.

Several procedures have been investigated as a minimally invasive treatment for lower urinary tract symptoms associated with BPH such as temporary prostatic urethral stents and the prostatic urethral lift (PUL). The PUL procedure involves the insertion of one or more permanent implants into the prostate, which retracts prostatic tissue and maintains an expanded urethral lumen. Temporarily implanted devices have been proposed as a minimally invasive alternative to transurethral resection of the prostate (TURP), considered the traditional standard treatment for symptomatic benign prostatic hyperplasia. The device is temporarily implanted into the obstructed prostatic urethra to facilitate tissue reshaping and improve urine outflow. Devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process.

Summary and Analysis of Evidence: Evidence for the use of a PUL who have lower urinary tract obstruction symptoms due to BPH and do not have sufficient response to medical therapy or are experiencing significant side effects with medical therapy includes systematic reviews, randomized controlled trials (RCTs), and nonrandomized studies. One RCT compared the PUL procedure with TURP and reported that the PUL procedure was noninferior for the study's composite endpoint, which required concurrent fulfillment of 6 independently validated measures of symptoms, safety, and sexual

health. While TURP was superior to PUL in managing lower urinary tract symptoms, PUL did provide significant symptom improvement over 2 years. PUL was further superior to TURP in preserving ejaculatory function. These findings were corroborated by another RCT (the LIFT study), which compared PUL with sham control. Patients underwent washout of BPH medications before enrollment. LIFT reported that patients with the PUL procedure, compared with patients who had sham surgery and no BPH medication, had greater improvements in lower urinary tract symptoms without worsened sexual function at 3 months. After 3 months, patients were given the option to have PUL surgery; 80% of the patients with sham procedures chose that option. Publications from this trial reported these findings were preserved in a subset of patients over 3 to 5 years; however, a high number of patients were either excluded or lost to follow-up during this time. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome. Individuals with BPH with lower urinary tract symptoms who receive a temporarily implanted nitinol device (eg, iTind), the evidence includes a meta-analysis, RCT, and single-arm, multicenter, international prospective studies. One network meta-analysis compared the safety and efficacy of various minimally-invasive treatments for lower urinary tract symptoms associated with BPH, finding that iTind may result in worse urologic symptoms scores compared to TURP at short-term follow-up. One RCT compared the iTind device with a sham procedure and reported an improvement of at least 3 points on the International Prostate Symptom Score (IPSS) scale at 3 months in 78.6% versus 60% of participants. However, corresponding changes in overall IPSS, IPSS quality of life, peak urinary flow rate, Sexual Health Inventory for Men (SHIM), and International Index of Erectile Function scores were not significantly different between groups. One single-arm study reported significant improvements in symptoms and functional outcomes through >4 years. A subsequent single-arm study enrolling men desiring to preserve ejaculatory function reported no significant change in the SHIM total score and a statistically significant improvement on the Male Sexual Health Questionnaire for Ejaculatory Dysfunction questionnaire at 6 months. No studies have directly compared iTind to established alternatives; however, an RCT comparing iTind with the UroLift prostratic urethral lift procedure is currently ongoing. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

POSITION STATEMENT:

Use of prostatic urethral lift in members with moderate-to-severe lower urinary tract obstruction due to benign prostatic hyperplasia, including lateral and median lobe hyperplasia, **meets the definition of medical necessity** when **ALL** of the following criteria are met:

1. Member has persistent or progressive lower urinary tract symptoms despite medical therapy over a trial period of no less than 4 weeks, or is unable to tolerate medical therapy;
2. Prostate gland volume is ≤100 mL (or cc)
3. Member does not have urinary retention related to conditions other than benign prostatic hyperplasia, urinary tract infection, or recent prostatitis (within past year) and
4. Member does not have a known allergy to nickel, titanium or stainless steel.

Use of prostatic urethral lift in all other situations is considered **experimental or investigational.** The evidence is insufficient to determine the effects of the technology on health outcomes.

Use of a temporary prostatic urethral stent, including an implantable nitinol device (iTind), is considered **experimental or investigational** for all indications. The evidence is insufficient to determine the effects of the technology on health outcomes.

BILLING/CODING INFORMATION

CPT Coding

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)
53855	Insertion of a temporary prostatic urethral stent, including urethral measurement (**Investigational**)

HCPCS Coding

C9739	Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants
C9740	Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants
C9769	Cystourethroscopy, with insertion of temporary prostatic implant/stent with fixation/anchor and incisional struts **(Investigational)**

ICD-10 Diagnosis Codes That Support Medical Necessity:

N40.1	Benign prostatic hyperplasia with lower urinary tract symptoms

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline reviewed date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request

DEFINITIONS:

No guideline specific definitions apply.

RELATED GUIDELINES:

None.

OTHER:

None.

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 09/26/24.

GUIDELINE UPDATE INFORMATION:

03/15/05	New Medical Coverage Guideline.
03/15/06	Annual review: continue investigational.
02/15/07	Scheduled review. No change in investigational status. Revised when services are covered; add “of temporary prostatic stent”. Added “temporary prostatic” to Billing/Coding Information section-ICD-9 diagnoses codes that support medical necessity. Updated references.
06/15/07	Reformatted guideline; references updated.
03/15/08	Annual review: position statement maintained, description section updated, references updated.
03/15/09	Annual review: position statement maintained and references updated.
01/01/10	Annual HCPCS coding update: added code 53855, deleted code 0084T.
03/15/10	Annual review: position statement maintained; description section and references updated.
02/15/11	Annual review: position statement maintained and references updated.
10/15/11	Scheduled review; position statement maintained, description section and references updated.
11/15/12	Annual review; position statement maintained and references updated.
09/15/13	Annual review; investigational position statement maintained and references updated.
08/15/14	Annual review; position statement maintained and references updated.
06/15/15	Annual review; position statement, billing/coding, description, guideline title and references updated.
04/15/16	Revision; position statements maintained and references updated
05/15/17	Revision; Investigational position statements maintained; description and references updated.

02/15/18	Annual review; PUL coverage statement added; description, coding, & references updated.
10/15/18	Review; Coverage criteria and references updated.
10/15/19	Review; *Prostate-specific antigen level ≥3 ng/mL* removed from PUL criteria; investigational temporary prostatic stent position maintained; and references updated.
10/01/20	Quarterly CPT/HCPCS coding update; added code C9769.
10/15/20	Review; Investigational position statement and references updated.
10/15/21	Review: Position statement and references updated.
10/25/21	Revision: Position statement updated.
03/15/22	Review: PUL criteria updated; references updated.
05/25/23	Update to Program Exceptions section.
10/15/23	Review: Position statement and references updated.
03/15/24	Revision: Position statement, references, and policy title updated.
10/15/24	Review: Position statements maintained; description and references updated.