Medical Coverage Policy | Temporarily Implanted Nitinol Device (iTind) for Benign Prostatic Hyperplasia

EFFECTIVE DATE: 05|01|2023
POLICY LAST REVIEWED: 02|18|2026

OVERVIEW

Benign prostatic hyperplasia (BPH) is a common condition in older individuals that can lead to increased urinary frequency, an urgency to urinate, a hesitancy to urinate, nocturia, and a weak stream when urinating. Temporarily implanted nitinol 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. The implant is typically removed after 5 to 7 days of treatment.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Medicare Advantage Plans

The use of a temporarily implanted nitinol device (eg, iTind) as a treatment of lower urinary tract symptoms due to benign prostatic hyperplasia is not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products

The use of a temporarily implanted nitinol device (eg, iTind) as a treatment of lower urinary tract symptoms due to benign prostatic hyperplasia is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

BACKGROUND

Benign Prostatic Hyperplasia

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. Benign prostatic hyperplasia prevalence increases with age and is present in more than 80% of individuals age 70 to 79 years.

Two scores are widely used to evaluate BPH-related symptoms: the American Urological Association Symptom Index (AUASI) and the International Prostate Symptom Score (IPSS). The AUASI is a self-administered 7-item questionnaire assessing the severity of various urinary symptoms. Total AUASI scores range from 0 to 35, with overall severity categorized as mild (≤7), moderate (8-19), or severe (20-35). The IPSS incorporates questions from the AUASI and a quality of life question or a "Bother score."

Benign prostatic hyperplasia does not necessarily require treatment. The decision on whether to treat BPH is based on an assessment of the impact of symptoms on quality of life along with the potential side effects of

treatment. For patients with moderate-to-severe symptoms (eg, an AUASI score of ≥8), bothersome symptoms, or both, a discussion about medical therapy is reasonable. Benign prostatic hyperplasia should generally be treated medically first. Available medical therapies for BPH-related lower urinary tract dysfunction include α-adrenergic blockers (eg, alfuzosin, doxazosin, tamsulosin, terazosin, silodosin), 5α-reductase inhibitors (eg, finasteride, dutasteride), combination α-adrenergic blockers and 5α-reductase inhibitors, anti-muscarinic agents (eg, darifenacin, solifenacin, oxybutynin), and phosphodiesterase-5 inhibitors (eg, tadalafil). In a meta-analysis of both indirect comparisons from placebo-controlled studies (n=6333) and direct comparative studies (n=507), Djavan et al (1999) found that the IPSS improved by30% to 40% and the Qmax score (mean peak urinary flow rate) improved by 16% to 25% in individuals assigned to α-adrenergic blockers. Combination therapy using an α-adrenergic blocker and 5α-reductase inhibitor has been shown to be more effective for improving IPSS than either treatment alone, with median scores improving by more than 40% over 1 year and by more than 45% over 4 years.

Patients who do not have sufficient response to medical therapy, or who are experiencing significant side effects with medical therapy, may be referred for surgical or ablative therapies. The American Urological Association (AUA) recommends surgical intervention for patients who have "renal insufficiency secondary to BPH, refractory urinary retention secondary to BPH, recurrent urinary tract infections (UTIs), recurrent bladder stones or gross hematuria due to BPH, and/or with lower urinary tract symptoms (LUTS) attributed to BPH refractory to and/or unwilling to use other therapies."Transurethral resection of the prostate (TURP) is generally considered the reference standard for comparisons of BPH procedures. In the perioperative period, TURP is associated with risks of any operative procedure (eg, anesthesia risks, blood loss). Although short-term mortality risks are generally low, a large prospective study with 10,654 patients by Reich et al (2008) reported the following short-term complications: "failure to void (5.8%), surgical revision (5.6%), significant urinary tract infection (3.6%), bleeding requiring transfusions (2.9%), and transurethral resection syndrome (1.4%)."Incidental carcinoma of the prostate was diagnosed by histologic examination in 9.8% of patients. In the longer term, TURP is associated with an increased risk of sexual dysfunction and incontinence.

The use of the iTind temporarily implanted nitinol device has been investigated as a minimally invasive treatment for lower urinary tract symptoms associated with BPH. With the use of a rigid cytoscope, the device is temporarily implanted into the obstructed prostatic urethra where 3 double intertwined nitinol struts configured in a tulip shape gradually expand. The resulting circumferential force facilitates tissue reshaping via ischemic necrosis of the mucosa, resulting in urethral expansion and prostatic incisions that function as longitudinal channels to improve urine outflow. The implant is typically removed after 5 to 7 days of treatment. A distal nylon wire facilitates device retrieval which may be approached using a snare to pull the device into either a cytoscope sheath or an open-ended silicone catheter (20-22 Fr). The first-generation TIND device had one extra strut and a pointed tip covered by a soft plastic material.

For individuals who have benign prostatic hyperplasia (BPH) with lower urinary tract symptoms who receive a temporarily implanted nitinol device (eg, iTind), the evidence includes a meta-analysis, 1 randomized controlled trial (RCT), and 2 single-arm, multicenter, international prospective studies. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, and treatment-related morbidity. 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 transurethral resection of the prostate (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, respectively (p=.029). 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 3>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.

CODING

Medicare Advantage Plans and Commercial Products

The following HCPCS code(s) is not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

53865 Cystourethroscopy with insertion of temporary device for ischemic remodeling (ie, pressure necrosis) of bladder neck and prostate

RELATED POLICIES

Not applicable

PUBLISHED

Provider Update, April 2026
Provider Update, April 2025
Provider Update, April 2024
Provider Update, March 2023

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