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

EFFECTIVE DATE: 05|01|2023
POLICY LAST UPDATED: 01|18|2023

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 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 IPSS scale at 3 months in 78.6% versus 60% of participants, respectively (p=.029). However, corresponding changes in overall IPSS, IPSS QoL, Qmax, SHIM, and IIEF scores were not significantly different between groups. One single-arm study reported significant improvements in symptoms and functional outcomes through 3 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 MSHQ-EjD 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 is not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

C9769 Cystourethroscopy, with insertion of temporary prostatic implant/stent with fixation/anchor and incisional struts

RELATED POLICIES

Prostatic Urethral Lift

Transurethral Water Jet Ablation (Aquablation) for Benign Prostatic Hypertrophy

PUBLISHED

Provider Update, March 2023

REFERENCES:

1. Sarma AV, Wei JT. Clinical practice. Benign prostatic hyperplasia and lower urinary tract symptoms. N Engl J Med. Jul 19 2012;367(3): 248-57. PMID 22808960
2. Barry MJ, Fowler FJ, O'Leary MP, et al. Measuring disease-specific health status in men with benign prostatic hyperplasia.Measurement Committee of The American Urological Association. Med Care. Apr 1995; 33(4 Suppl): AS145-55. PMID7536866
3. O'leary MP. Validity of the "bother score" in the evaluation and treatment of symptomatic benign prostatic hyperplasia. Rev Urol.2005; 7(1): 1-10. PMID 16985801
4. Djavan B, Marberger M. A meta-analysis on the efficacy and tolerability of alpha1-adrenoceptor antagonists in patients withlower urinary tract symptoms suggestive of benign prostatic obstruction. Eur Urol. 1999; 36(1): 1-13. PMID 10364649
5. Lerner LB, McVary KT, Barry MJ, et al. Management of Lower Urinary Tract Symptoms Attributed to Benign ProstaticHyperplasia: AUA GUIDELINE PART II-Surgical Evaluation and Treatment. J Urol. Oct 2021; 206(4): 818-826. PMID 34384236
6. Foster HE, Barry MJ, Dahm P, et al. Surgical Management of Lower Urinary Tract Symptoms Attributed to Benign ProstaticHyperplasia: AUA Guideline. J Urol. Sep 2018; 200(3): 612-619. PMID 29775639
7. Reich O, Gratzke C, Bachmann A, et al. Morbidity, mortality and early outcome of transurethral resection of the prostate: aprospective multicenter evaluation of 10,654 patients. J Urol. Jul 2008; 180(1): 246-9. PMID 18499179
8. Amparore D, De Cillis S, Volpi G, et al. First- and Second-Generation Temporary Implantable Nitinol Devices As MinimallyInvasive Treatments for BPH-Related LUTS: Systematic Review of the Literature. Curr Urol Rep. Jul 05 2019; 20(8): 47. PMID31278441
9. Fiori C, De Cillis S, Volpi G, et al. iTIND for BPH: Technique and procedural outcomes: A narrative review of current literature.Turk J Urol. Nov 2021; 47(6): 470-481. PMID 35118965
10. Balakrishnan D, Jones P, Somani BK. iTIND: the second-generation temporary implantable nitinol device for minimally invasivetreatment of benign prostatic hyperplasia. Ther Adv Urol. 2020; 12: 1756287220934355. PMID 32655690
11. Rosen RC, Catania JA, Althof SE, et al. Development and validation of four-item version of Male Sexual Health Questionnaireto assess ejaculatory dysfunction. Urology. May 2007; 69(5): 805-9. PMID 17482908
12. Cappelleri JC, Rosen RC. The Sexual Health Inventory for Men (SHIM): a 5-year review of research and clinical experience. IntJ Impot Res. 2005; 17(4): 307-19. PMID 15875061
13. Sønksen J, Barber NJ, Speakman MJ, et al. Prospective, randomized, multinational study of prostatic urehral lift versustransurethral resection of the prostate: 12-month results from the BPH6 study. Eur Urol. Oct 2015; 68(4): 643-52. PMID25937539
14. Barry MJ, Williford WO, Chang Y, et al. Benign prostatic hyperplasia specific health status measures in clinical research: howmuch change in the American Urological Association symptom index and the benign prostatic hyperplasia impact index isperceptible to patients?. J Urol. Nov 1995; 154(5): 1770-4. PMID 7563343

15. Roehrborn CG, Wilson TH, Black LK. Quantifying the contribution of symptom improvement to satisfaction of men withmoderate to severe benign prostatic hyperplasia: 4-year data from the CombAT trial. J Urol. May 2012; 187(5): 1732-8. PMID22425127
16. Porpiglia F, Fiori C, Bertolo R, et al. Temporary implantable nitinol device (TIND): a novel, minimally invasive treatment for reliefof lower urinary tract symptoms (LUTS) related to benign prostatic hyperplasia (BPH): feasibility, safety and functional results at1 year of follow-up. BJU Int. Aug 2015; 116(2): 278-87. PMID 25382816
17. Porpiglia F, Fiori C, Bertolo R, et al. 3-Year follow-up of temporary implantable nitinol device implantation for the treatment ofbenign prostatic obstruction. BJU Int. Jul 2018; 122(1): 106-112. PMID 29359881
18. Franco JV, Jung JH, Imamura M, et al. Minimally invasive treatments for lower urinary tract symptoms in men with benignprostatic hyperplasia: a network meta-analysis. Cochrane Database Syst Rev. Jul 15 2021; 7(7): CD013656. PMID 34693990
19. Chughtai B, Elterman D, Shore N, et al. The iTind Temporarily Implanted Nitinol Device for the Treatment of Lower Urinary TractSymptoms Secondary to Benign Prostatic Hyperplasia: A Multicenter, Randomized, Controlled Trial. Urology. Jul 2021; 153:270-276. PMID 33373708
20. Porpiglia F, Fiori C, Amparore D, et al. Second-generation of temporary implantable nitinol device for the relief of lower urinarytract symptoms due to benign prostatic hyperplasia: results of a prospective, multicentre study at 1 year of follow-up. BJU Int.Jun 2019; 123(6): 1061-1069. PMID 30382600
21. Kadner G, Valerio M, Giannakis I, et al. Second generation of temporary implantable nitinol device (iTind) in men with LUTS:2 year results of the MT-02-study. World J Urol. Dec 2020; 38(12): 3235-3244. PMID 32124019
22. Amparore D, Fiori C, Valerio M, et al. 3-Year results following treatment with the second generation of the temporaryimplantable nitinol device in men with LUTS secondary to benign prostatic obstruction. Prostate Cancer Prostatic Dis. Jun2021; 24(2): 349-357. PMID 33005003
23. De Nunzio C, Cantiello F, Fiori C, et al. Urinary and sexual function after treatment with temporary implantable nitinol device(iTind) in men with LUTS: 6-month interim results of the MT-06-study. World J Urol. Jun 2021; 39(6): 2037-2042. PMID32851439
24. National Institute for Health and Care Excellence (NICE). Interventional procedures guidance: prostatic urethral temporaryimplant insertion for lower urinary tract symptoms caused by benign prostatic hyperplasia [IPG737]. September 21, 2022;https://www.nice.org.uk/guidance/ipg737. Accessed November 15, 2022.