



FEP Medical Policy Manual

FEP 7.01.175 Temporarily Implanted Nitinol Device (iTind) for Benign Prostatic Hyperplasia

Annual Effective Policy Date: April 1, 2024

Original Policy Date: December 2022

Related Policies:

2.01.49 - Transurethral Water Vapor Thermal Therapy and Transurethral Water Jet Ablation (Aquablation) for Benign Prostatic Hypertrophy
7.01.151 - Prostatic Urethral Lift

Temporarily Implanted Nitinol Device (iTind) for Benign Prostatic Hyperplasia

Description

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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.

OBJECTIVE

The objective of this evidence review is to determine whether a temporarily implanted nitinol device improves the net health outcome in individuals with benign prostatic hyperplasia and lower urinary tract symptoms.

POLICY STATEMENT

The use of a temporarily implanted nitinol device (eg, iTind) is considered **investigational** as a treatment of lower urinary tract symptoms due to benign prostatic hyperplasia.

POLICY GUIDELINES

None

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

In April 2019, the iTind System (Olympus; previously, Medi-Tate Ltd., Hadera, Israel) was granted a de novo 510(k) classification by the U.S. Food and Drug Administration (FDA) (DEN190020; product code: QKA). The new classification applies to this device and substantially equivalent devices of this generic type (eg, K210138). The iTind System is intended for the treatment of symptoms due to urinary outflow obstruction secondary to BPH in men age 50 years and older.

RATIONALE

Summary of Evidence

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 >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 prostatic urethral lift procedure is currently ongoing. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Urological Association

In 2021, the American Urological Association (AUA) published guidelines on the surgical evaluation and treatment of lower urinary tract symptoms (LUTS) attributed to benign prostatic hyperplasia (BPH).⁵ These guidelines do not address the use of temporarily implanted nitinol devices.

A 2023 amendment to the 2021 AUA guideline stated that temporary implanted prostatic devices are an option for individuals with BPH, LUTS, prostate volume of 25 to 75 grams, and who lack an obstructive median lobe.²⁵ This recommendation was based on expert opinion due to an absence of sufficient evidence.

National Institute for Health and Care Excellence

In 2022, the National Institute for Health and Care Excellence (NICE) issued an interventional procedures guidance on prostatic urethral temporary implant insertion for lower urinary tract symptoms caused by BPH.²⁶ The recommendation noted that the evidence on the use of these devices is limited in quantity and quality. Therefore, the procedure should only be used with special arrangements for clinical governance, consent, and audit or research.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
March 2023	New policy - Add to Urology section	Policy created with literature review through November 15, 2022. The use of a temporarily implanted nitinol device (eg, iTind) is considered investigational as a treatment of lower urinary tract symptoms due to benign prostatic hyperplasia.
March 2024	Replace policy	Policy updated with literature review through November 17, 2023. Policy statements unchanged.