07.01.95 Temporarily Implanted Nitinol Device (iTind) for Benign Prostatic Hyperplasia

Original Effective Date: July2015

Review Date: February 2026

Revised: October 2023

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Related Policies:

- 02.01.53 High Intensity Focused Ultrasound (HIFU)
- 07.01.94 Prostatic Urethral Lift
- 07.01.96 Transurethral Water Vapor Thermal Therapy (Rezum) and Transurethral Water Jet Ablation (Aquablation) for Benign Prostatic Hypertrophy
- 07.01.97 Miscellaneous Minimally Invasive Treatments for Benign Prostatic Hyperplasia

Summary

Description

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 BPH. 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.

Summary of Evidence

For individuals who have BPH with lower urinary tract symptoms who receive a temporarily implanted nitinol device (e.g.,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 (QOL), 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 Dysfunction (IIEF) 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 (MSHQ-EjD) 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.

Additional Information

Not applicable.

OBJECTIVE

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

PRIOR APPROVAL

Not applicable.

POLICY

The use of temporarily implanted nitinol device (e.g., iTind) is considered **investigational** as a treatment of lower urinary tract symptoms due to benign prostatic hyperplasia (BPH). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

POLICY GUIDELINES

Coding

See the Codes table for details.

BACKGROUND

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. BPH prevalence increases with age and is present in more than 80% of individuals aged 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."

BPH does not necessarily require treatment. The decision on whether to treat BPH is based on an assessment of the impact of symptoms on QOL along with the potential side effects of treatment. For patients with moderate-to-severe symptoms (e.g., an AUASI score of ≥8), bothersome symptoms, or both, a discussion about medical therapy is reasonable. BPH should generally be treated medically first. Available medical therapies for BPH-related lower urinary tract dysfunction include α-adrenergic blockers (e.g., alfuzosin, doxazosin, tamsulosin, terazosin, silodosin), 5α-reductase inhibitors (e.g., finasteride, dutasteride), combination α-adrenergic blockers and 5α-reductase inhibitors, anti-muscarinic agents (e.g., darifenacin, solifenacin, oxybutynin), and phosphodiesterase-5 inhibitors (e.g., 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 by 30% 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.

Individuals 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 (e.g., 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 iTind device had one extra strut and a pointed tip covered by a soft plastic material.

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 (e.g., K210138). The iTind System is intended for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men aged 50 years and older.

RATIONALE

This evidence review was created in July 2015 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through January2026.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Temporarily Implanted Nitinol Device

Clinical Context and Therapy Purpose

The purpose of temporarily implanted nitinol device (iTind) in individuals who have lower urinary tract symptoms due to benign prostatic hyperplasia (BPH) is to provide a treatment option that is an alternative to or an improvement on existing therapies such as medical management, transurethral resection of the prostate (TURP), or prostatic urethral lift (PUL).

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals who are experiencing lower urinary tract symptoms without a history suggesting non-BPH causes of the symptoms and who do not have a sufficient response to medical therapy or are experiencing significant side effects with medical therapy.

Interventions

The therapy being considered is temporary implantation of a nitinol device (eg, iTind system).The iTind system consists of a nitinol-based implant, delivery system, and retrieval kit. The device is temporarily implanted into the obstructed prostatic urethra where it assumes its expanded configuration to facilitate tissue reshaping and improve urine outflow. The implant is typically removed after 5 to 7 days of implantation.

Comparators

The following practices are currently being used to treat BPH in this setting:

- Conservative treatment, including watchful waiting and lifestyle modifications;
- Pharmacotherapy;
- TURP, which is generally considered the reference standard for comparisons of BPH procedures; and
- PUL.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, health status measures, QOL, and treatment-related morbidity.

The International Prostate Symptom Score (IPSS) is used to assess the severity of BPH symptoms. The first 7 questions address urinary frequency, nocturia, weak urinary stream, hesitancy, intermittence, incomplete emptying, and urgency each on a scale of 0 to 5. The total score, summed across the 7 items measured, ranges from 0 (no symptoms) to 35 (most severe symptoms). A decrease in score indicates improvement.

A number of health status measures are used to evaluate symptoms relevant to BPH and adverse events of treatment for BPH, including urinary symptoms, urinary dysfunction measured by peak urinary flow rate (Qmax), ejaculatory dysfunction, overall sexual health, and overall quality of life. Qmax is measured by

uroflowmetry; low rates are associated with more voiding dysfunction and rates <10 mL/sec are considered obstructed. Urinary continence may be assessed via the Incontinence Symptom Index (ISI) questionnaire. Erectile and ejaculatory function is assessed in sexually active men only. Scales include the International Index of Erectile Function (IIEF) and the Male Sexual Health Questionnaire for Ejaculatory Dysfunction (MSHQ-EjD).

Quality of life is assessed with various scales including the IPSS-QoL.

Both short-term (up to 12 months) and long-term (12 months and longer) outcomes should be assessed. Treatment-related morbidity can also be assessed in the immediate post-procedure period.

Some validated patient-reported scales are summarized in Table 1.

Table 1. Patient-Reported Health Outcomes Measures Relevant to Benign Prostatic Hyperplasia

Measure	Outcome Evaluated	Description	Clinically Meaningful Difference (If Known)
Male Sexual Health Questionnaire for Ejaculatory Dysfunction (MSHQ-EjD)	Ejaculatory function and quality of life	Patient-administered, 4-item scale. Symptoms rated as absent (15) to severe (0). QOL assessed as no problem (0) to extremely bothered (5).	NR
Sexual Health Inventory for Men (SHIM)	Erectile function	Patient-administered, 5-item scale. Erectile dysfunction rated as severe (1-7), moderate (8-11), mild to moderate (12-16), or mild (17-21). Fewest symptoms present for patients with scores 22-25.	5-point change
American Urological Association Symptom Index (AUASI); International Prostate Symptom Score (IPSS)	Severity of lower urinary tract symptoms	Patient-administered, 7-item scale. Symptoms rated as mild (0-7), moderate (8-19), or severe (20-35). IPSS asks an additional question, rating QOL as delighted (0) to terrible (6).	• Minimum of 3-point change • Minimum of 30% change
Benign Prostatic Hyperplasia Impact Index (BII)	Effect of urinary symptoms on health domains	Patient-administered, 4-item scale. Symptoms rated as absent (0) to severe (13).	Minimum of 0.4-point change

QOL: quality of life; NR: not reported.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.

- Studies with duplicative or overlapping populations were excluded.
- Studies concerning older versions of the technology that are no longer commercially marketed were excluded, including Porpiglia et al (2015) and Porpiglia et al (2018).

Review of Evidence

Systematic Reviews

In 2021, Franco et al published a Cochrane network meta-analysis assessing the comparative effectiveness of minimally invasive treatments for lower urinary tract symptoms in men with BPH. Twenty-seven trials representing 3017 men were included through February 2021. Compared to TURP at short-term follow-up, temporary implantable nitinol devices (TIND) may result in worse urologic symptoms scores (mean difference [MD] of IPSS score, 7.5; 95% CI, 0.68 to 15.69; low-certainty evidence) and little to no difference in quality-of-life scores (MD, 0.87; 95% CI, -1.04 to 2.79; low-certainty evidence).

Randomized Controlled Trials

Chughtai et al (2021) published the results of a multicenter, single-blinded RCT of the iTind implant compared to sham for the treatment of lower urinary tract symptoms secondary to BPH. Study characteristics and results are summarized in Tables 2 and 3. Fifty-seven participants received sham treatment, and out of 128 participants randomized to receive iTind, 10 did not undergo the procedure. The primary endpoint was the response rate, defined as the percentage of patients achieving a reduction of at least 3 points on the IPSS scale at 3 months. Patients were unblinded to their treatment after the 3-month follow-up visit. Mean patient age was 61.1 years and baseline characteristics were similar between groups, except for a higher Charlson Comorbidity Index score among iTind recipients (2.52 vs. 1.26; p<.001). While a significantly higher proportion of patients treated with iTind achieved the primary endpoint compared to sham at 3 months (78.6% vs. 60%; p=.029), changes in overall IPSS, IPSS- QoL, Qmax, Sexual Health Inventory for Men (SHIM), and IIEF scores were not statistically different between groups. Patients treated with iTind were followed through 12 months. Of 78 iTind subjects in the per-protocol population, a mean reduction of 9.25 points on the IPSS was found at 12 months, suggesting durability of treatment. A total of 16 serious adverse events among 10 subjects was reported within 0-30 days in the iTind group compared to 2 events in 2 subjects in the sham group. In the iTind group, a total of 5 serious adverse events were classified as device- or procedure-related, including urinary retention (n=2), urinary tract infection (n=2) and sepsis (n=1). Six individuals (4.7%) had an alternative BPH surgery during 12-month follow-up due to deterioration of symptoms. An additional 6 participants (4.7%) resumed medication for symptomatic BPH. Study relevance, design, and conduct limitations are summarized in Tables 4 and 5. An RCT comparing the iTind device to the UroLift (PUL) procedure is ongoing (NCT04757116).

Table 2. Summary of Key Randomized Controlled Trial Characteristics

Study	Countries	Sites	Dates	Participants[2]	Interventions[1]	
					Active	Comparator
Chughtai et al (2021)	US, Canada	16	2015-2018	Men ≥ 50 years with IPSS ≥10, PFR ≤12 mL/s with a 125 mL voided volume, prostate volume 25 to 75 mL, and normal urinalysis, CBC, and biochemistry panel. Exclusion criteria included subjects with PVR >250 mL, obstructive median lobe,	iTind device (second generation device, deployed via rigid	Sham (insertion and removal of an 18F silicone Foley catheter)

				PSA >10 ng/mL or free PSA <25%, previous prostate surgery, prostate or bladder cancer, neurogenic bladder and/or sphincter abnormalities, confounding bladder pathologies, recent cystolithiasis or hematuria, active UTI, compromised renal function, known immunosuppression, active antithrombotic or antiplatelet treatment, cardiac disease, including arrhythmias and uncontrolled diabetes mellitus. Participants were required to wash-out from BPH-related medications as follows: 1 month for α-blockers and 6 months for 5-α-reductase inhibitors. Medication naïve patients were allowed to participate.	cytoscope) (n=128)	(n=57)

BPH: benign prostatic hypertrophy; CBC: complete blood count; IPSS: International Prostate Symptom Score; PFR: peak urinary flow rate; PSA: prostate specific antigen; PVR: post-void residual; UTI: urinary tract infection.
[1] Number randomized; intervention; mode of delivery; dose (frequency/duration).
[2] Key eligibility criteria.

Table 3. Summary of Key Randomized Controlled Trial Results

Study	IPSS ≥ 3 Response Rate (%)	IPSS (95% CI)	IPSS QoL (95% CI)	Qmax (mL/s) (95% CI)	SHIM/IIEF (95% CI)
Chughtai et al (2021)	N=185	N=185	N=185	N=185	N=185
Change from baseline at 3 months (ITT population)					
iTind	78.6%	-9.0	-1.9	4.4	Unchanged
Sham	60.0%	-6.6	-1.5	2.9	Unchanged
MD (95% CI); p	18.6%; p=.029	2.4; p=.063	0.4; p=.264	1.5; p=.230	NR
Change from baseline at 12 months (PP population)		N=78	N=78	N=55	N=78/77
iTind	NR	-9.25 (-11.0 to -7.4; p<.0001)	-1.90 (-2.2 to -1.4; p<.0001)	3.52 (2.0 to 5.0; p<.0001)	0.45 (-1.0 to 1.9; p=0.32)/ 4.51 (0.2 to 8.8; p=.01)
Sham	NA	NA	NA	NA	NA
MD (95% CI); p	NA	NA	NA	NA	NA

CI: confidence interval; IIEF: International Index of Erectile Function; IPSS: International Prostate Symptom Score; ITT: intention-to-treat; MD: mean difference; NA: not applicable; NR: not reported; PP: per-protocol; Qmax: peak flow rate; QoL: quality of life; SHIM: Sexual Health Inventory for Men.

Table 4. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
Chughtai et al (2021)	3. Unclear what proportion of participants was medication naïve. 4. Study racial and ethnic demographics not reported.		2. Comparison to an active comparator is of interest. 3. Sham treatment was administered via silicone Foley catheter versus rigid cytoscope.		1. Not sufficient duration for benefit.

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4. Enrolled populations do not reflect relevant diversity; 5. Other.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5. Other.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 5. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Chughtai et al (2021)		1. Study staff not blinded.		1. Approximately 30% of patients in both treatment arms were lost to follow-up. 2. Missing at random assumption to handle missing data may not be appropriate. 7. Unclear exclusions in per protocol population.		3. Reporting of confidence intervals was missing or unclear. 4. Comparative treatment effects were not calculated through 12 months.

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias; 5. Other.
[b] Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials); 7. Other.
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5. Other.

Single-Arm Studies

Dimitri et al 2025 published a cohort study of 120 patients who had symptomatic BPH and were unresponsive to alpha-blockers who were treated with iTind.[7] Study characteristics and results are summarized in Tables 6 and 7. At enrollment, patients mean (standard deviation [SD]) age was 52.9 (7.9) years with mean (SD) prostate volume of 40.3 (11.25) mL. Mean (SD) Qmax and post-void residual (PVR) were 7.6 (2.6) mL/sec and 72.3 (35.2) mL, respectively. The reported mean (SD) IPSS-QoL was 6 (2.5) and a mean urinary symptom IPSS of 21.5 (5.1). By 3 months of follow-up, IPSS, IPSS-QoL, PVR, and

Qmax were significantly improved compare to baseline and improvements continued to 12 months. No patients reported ejaculatory or sexual dysfunction at final followup.

MT-02 Cohort

Eighty-one subjects with lower urinary tract symptoms due to BPH were implanted with the second-generation iTind device and followed for up to >4 years. Study characteristics and results are summarized in Tables 6 and 7. Mean (SD) patient age was 65 (8.9) years with mean (SD) prostate volume 40.5 (12.25) mL, Qmax 7.3 (2.6) mL/s, and IPSS score 22.5 (5.6). Devices were retrieved at a mean (SD) of 5.9 (1.1) days after implantation and no intraoperative complications were reported. At the 6-month and 12-month visits, 85.2% and 88.9% of treated patients reported a 3-point or greater improvement in IPSS, respectively. Compared to baseline, none of the 61 sexually active participants who completed a 12-month, 2-item questionnaire reported sexual or ejaculatory dysfunction. Statistically significant improvements in total IPSS, Qmax, IPSS-QoL, and post-void residual (PVR) volume were observed through 36 months, and IPSS and IPSS-QOL through >48 months (mean 60.2 months). Clavien-Dindo grade I, II, and IIIa treatment-related adverse events were reported in 33 (41%), 5 (6.2%), and 8 (9.9%) patients within the first month post-treatment, respectively. The most common adverse events were hematuria (12.3%), urinary urgency (11.1%), acute urinary retention (9.9%), and pain (9.9%). No further adverse events were reported during long-term follow-up. From baseline through 36 months, 12 (14.8%) patients were considered treatment failures, of which 7 were later found to have obstructive median lobes ($p<.0001$). Subsequent drug therapy was required in 5 (6.2%) patients and 8 (8.6%) underwent surgical retreatment via TURP or laser. Sexually active patients who completed a 2-item questionnaire reported no sexual or ejaculatory dysfunction through 3 years. Between 36 and >48 months, 2 additional patients underwent surgical treatment; therefore, the total retreatment rate from baseline to >48 months was 11.1%.

MT-06 Cohort

De Nunzio et al (2021) reported 6-month interim outcomes for 70 subjects with lower urinary tract symptoms due to BPH seeking to preserve ejaculatory function who were implanted with the second-generation iTind device. Study characteristics and results are summarized in Tables 6 and 7. Mean patient age was 62.3 years with mean prostate volume 37.68 mL, Qmax 7.3, and IPSS urinary symptoms score 21.2. At 6 months, statistically significant improvements were seen in IPSS urinary symptoms, IPSS QoL, Qmax, and MSHQ-EjD. No significant changes in PVR volume, SHIM total score, or ISI total score were reported. Clavien-Dindo grade I, IIIa, and IIIb treatment-related adverse events were reported in 53 (75.7%), 3 (4.3%), and 1 (1.4%) patient(s), respectively. The most common adverse events were transient hematuria (18.6%), dysuria (17%), urinary urgency (12.8%), and pain (11.4%). Follow-up is planned for 3 years.

Table 6. Summary of Key Single-Arm Study Characteristics

Cohort; Study	Study Type	Country	Dates	Participants	Treatment	Follow-Up
Dimitri et al (2025)	Retrospective	Italy	2019 - 2023	Men with symptomatic BPH with an IPSS ≥10, Qmax ≤12 mL/s, and prostate volume <50 mL. Individuals with neurogenic bladder,	iTind device (second generation device; deployed under light sedation via rigid cystoscope) (N=120)	12 months

				urethral strictures, PVR volume >80 mL, urinary bladder stones, prostate cancer, obstructive median lobe, and previous prostate surgery were excluded. Participants were required to wash-out from BPH-related medications as follows: 1 month for α-blockers and 6 months for 5-α-reductase inhibitors.		
MT-02 (Porpiglia et al [2019]; Kadner et al, 2021]; Amparore et al [2023])	Prospective	Belgium, Italy, Spain, Switzerland, United Kingdom	2014 - 2020	Men with symptomatic BPH with an IPSS ≥10, Qmax ≤12 mL/s, and prostate volume <75 mL. Individuals with hemostatic disorders, neurogenic bladder and/or sphincter abnormalities, impaired renal function, history of urethral strictures, PVR volume >250 mL, urinary bladder stones, bladder cancer, obstructive median lobe, active UTI, and previous prostate surgery were excluded. Participants were required to wash-out from BPH-related medications as follows: 1 month for α-blockers and 6 months for 5-α-reductase inhibitors.	iTind device (second generation device; deployed under light sedation via rigid cystoscope) (N=81)	12 months 24 months 36 months
MT-06 (De Nunzio et al [2021])	Prospective	Australia, France, Germany, Italy, Spain, Switzerland	2018 - 2019	Men with symptomatic BPH looking to preserve their ejaculatory function with an IPSS ≥10, Qmax ≤12 mL/s, prostate volume <120 mL, and normal urinalysis and urine culture. Individuals with previous prostate surgery, prostate cancer, urethral stricture, bladder stones, UTI, obstructing	iTind device (second generation device; deployed under light sedation via rigid cystoscope) (N=70)	6 months

				median lobe (>1.2 cm), and neurological conditions potentially affecting voiding function were excluded. Patients were not washed out of drug therapy for BPH and did not stop anti-coagulation or anti-platelet therapy before the procedure. All patients discontinued BPH drug therapy after device retrieval.		

BPH: benign prostatic hyperplasia; IPSS: International Prostate Symptom Score; PVR: post-void residual; Qmax: peak flow rate; UTI: urinary tract infection.

Table 7. Summary of Key Single-Arm Study Results

Cohort; Study	Mean Total IPSS	Mean Qmax, mL/s	Mean IPSS - Urinary Symptoms	Mean IPSS-QoL	Mean PVR, mL
Dimitri et al (2025)	120	120	NR	120	120
Baseline (SD)	21.5 (5.1)	7.6 (2.6)	NR	6.0 (2.5)	72.3 (35.2)
12 months (SD)	9.7 (5.5)	15.7 (.1)	NR	3.9 (0.8)	62.5 (15.9)
p	<.001	<.001	NR	<.001	<.001
MT-02	N	N	N	N	N
Porpiglia et al (2019); 12 months	67	67	67	67	67
Baseline (SD)	25.67 (6.04)	7.61 (2.25)	21.70 (5.56)	4 (2-5) (median [IQR])	73.54 (49.54)
Change (SD)	-15.30 (8.00)	7.30 (8.20)	-12.92 (6.92)	-3 (NR)	-39.51 (57.46)
95% CI; p	-17.29 to -13.30; <.001	5.22 to 9.38; <.001	-14.65 to -11.19; <.001	NR; <.001	-53.98 to -25.04; <.001
Kadner et al (2020); 24 months	51	51	51	51	51

Cohort; Study	Mean Total IPSS	Mean Qmax, mL/s	Mean IPSS - Urinary Symptoms	Mean IPSS-QoL	Mean PVR, mL
Baseline (SD)	20.51 (4.58)	7.62 (2.25)	NR	3.96 (0.87)	65.84 (38.46)
Change (SD)	-12.00 (6.12)	8.38 (7.93)	NR	-2.20 (1.46)	-51.58 (36.68)
95% CI; p	-13.72 to -10.28; <.0001	6.13 to 10.63; <.0001	NR	-2.61 to -1.79; <.0001	-62.00 to -41.16; <.0001
Amparore et al (2021); 36 months	50	50	50	50	50
Baseline (SD)	20.69 (4.58)	7.71 (2.26)	NR	3.96 (0.87)	68.58 (39.53)
Change (SD)	-12.14 (6.95)	7.49 (6.86)	NR	-2.20 (1.46)	-59.21 (37.75)
95% CI; p	-67.4% to -49.0%; <.0001	83.2% to 146.2%; <.0001	NR	-66.2% to -45.0%; <.0001	-94.6% to -76.3%; <.0001
Amparore et al (2023); >48 months	41	41	41	41	41
Baseline (SD)	20.56 (4.42)	NR	NR	4.00 (0.89)	NR
Change (SD)	-9.29 (7.63)	NR	NR	-1.90 (1.59)	NR
95% CI; p	-56.5% to -34.1%; <.0001	NR	NR	-57.6% to -32.7%; <.0001	NR
MT-06	N	N	N	N	N
De Nunzio et al (2021); 6 months	70	70	70	70	70
Baseline (SD)	NR	7.3 (2.2)	21.2 (6.0)	4.1 (1.0)	69.3 (86.8)
Change (SD)	NR	4.6 (5.5)	-12.7 (6.9)	-2.2 (1.6)	-22.6 (77.3)
95% CI; p	NR	NR; <.01	NR; <.01	NR; <.01	NR;.12

CI: confidence interval; IPSS: International Prostate Symptom Score; IQR: interquartile range; NR; not reported; PVR: post-void residual; Qmax: peak urinary flow rate; QoL: quality of life; SD: standard deviation.

Section Summary: Temporarily Implanted Nitinol Device

The prospective, international, multicenter, single-arm MT-02 prospective study of the iTind device has reported statistically significant improvements in total IPSS score and IPSS - QoL score through >4 years, and Qmax, and PVR volume through 3 years. The subsequent single-arm MT-06 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. One RCT comparing the iTind device to sham treatment 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, changes in overall IPSS, IPSS QoL, Qmax, SHIM, and IIEF scores were not significantly different between groups. Major limitations of the RCT include high loss to follow-up (~30% in each treatment arm) and short duration of follow-up. An RCT comparing the iTind device to the UroLift (PUL) procedure is ongoing (NCT04757116).

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

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). These guidelines do not address the use of temporarily implantable implants (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. 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. 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.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review can be located at clinicaltrials.gov.

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CODES

To report provider services, use appropriate CPT codes, HCPCS codes, Revenue codes, and/or ICD diagnosis codes.

Codes	Number	Description
CPT		
	53865	Cystourethroscopy with insertion of temporary device for ischemic remodeling (i.e., pressure necrosis) of bladder neck and prostate
	53866	Catheterization with removal of temporary device for ischemic remodeling (i.e., pressure necrosis) of bladder neck and prostate
HCPCS		
	None	
Type of Service	Surgery	
Place of Service	Outpatient	

POLICY HISTORY

Date	Reason	Action
February 2026	Annual Review	Policy Renewed
February 2025	Annual Review	Policy Renewed
February 2024	Annual Review	Policy Renewed
October 2023	Interim Review	Policy Revised – content moved from retired policy “Treatments of Benign Prostatic Hyperplasia (BPH)”
February 2023	Annual Review	Policy Revised

Date	Reason	Action
September 2022	Interim Review	Policy Revised
February 2021	Annual Review	Policy Revised
July 2020	Interim Review	Policy Revised
February 2020	Annual Review	Policy Revised
February 2019	Annual Review	Policy Revised
February 2018	Annual Review	Policy Revised
September 2017	Interim Review	Policy Revised
June 2017	Annual Review	Policy Revised
June 2016	Annual Review	Policy Revised
July 2015		New Medical Policy

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
PO Box 9232
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