

<b>7.01.175 Temporarily Implanted Nitinol Device (iTind) for Benign Prostatic Hyperplasia</b>			
<b>Original Policy Date:</b>	February 1, 2023	<b>Effective Date:</b>	February 1, 2023
<b>Section:</b>	7.0 Surgery	<b>Page:</b>	Page 1 of 15

## Policy Statement

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

**NOTE:** Refer to [Appendix A](#) to see the policy statement changes (if any) from the previous version.

## Policy Guidelines

### Coding

The following HCPCS code is specific for Temporarily Implanted Nitinol Device (iTind):

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

## 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 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.

## Related Policies

- N/A

## Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

## 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 age 50 and older.

## Rationale

### 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.<sup>1</sup>

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.<sup>2</sup> Total AUASI scores range from 0 to 35, with overall severity categorized as mild ( $\leq 7$ ), moderate (8-19), or severe (20-35).<sup>1</sup> The IPSS incorporates questions from the AUASI and a quality of life question or a "Bother score."<sup>3</sup>

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 (e.g., an AUASI score of  $\geq 8$ ), 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  $\alpha$ -adrenergic blockers (e.g., alfuzosin, doxazosin, tamsulosin, terazosin, silodosin),  $5\alpha$ -reductase inhibitors (e.g., finasteride, dutasteride), combination  $\alpha$ -adrenergic blockers and  $5\alpha$ -reductase inhibitors, anti-muscarinic agents (e.g., darifenacin, solifenacin, oxybutynin), and phosphodiesterase-5 inhibitors (e.g., tadalafil).<sup>1</sup> 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  $\alpha$ -adrenergic blockers.<sup>4</sup> Combination therapy using an  $\alpha$ -adrenergic blocker and  $5\alpha$ -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."<sup>5</sup> Transurethral resection of the prostate (TURP) is generally considered the reference standard for comparisons of BPH procedures.<sup>6</sup> 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%)."<sup>7</sup> 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.<sup>8</sup> 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.<sup>9</sup> 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 cystoscope sheath or an open-ended silicone catheter (20–22 Fr).<sup>10</sup> The first-generation TIND device had one extra strut and a pointed tip covered by a soft plastic material.

### **Literature Review**

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 devices in patients 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 men 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 (e.g., 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;

- Transurethral resection of the prostate (TURP), which is generally considered the reference standard for comparisons of BPH procedures; and
- Prostatic urethral lift.

### Outcomes

The general outcomes of interest are symptoms, functional outcomes, health status measures, quality of life, 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 (Q<sub>max</sub>), ejaculatory dysfunction, overall sexual health, and overall quality of life. Q<sub>max</sub> 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 and the Male Sexual Health Questionnaire.

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 Outcome Measures Relevant to Benign Prostatic Hyperplasia**

Measure	Outcome Evaluated	Description	Clinically Meaningful Difference (If Known)
Male Sexual Health Questionnaire for Ejaculatory Dysfunction (MSHQ-EjD) <sup>11</sup>	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) <sup>12</sup>	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 <sup>13</sup> .
American Urological Association Symptom Index (AUASI); International Prostate Symptom Score (IPSS) <sup>1,3,14</sup>	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).	<ul style="list-style-type: none"> <li>• Minimum of 3-point change<sup>14,1</sup>.</li> <li>• Minimum of 30% change<sup>15</sup>.</li> </ul>
Benign Prostatic Hyperplasia Impact Index (BII) <sup>2</sup>	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 <sup>14</sup> .

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)<sup>16</sup> and Porpiglia et al (2018).<sup>17</sup>

## 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.<sup>18</sup> 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 benign prostatic hyperplasia.<sup>19</sup> 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, 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 prostatic urethral lift (PUL) procedure is ongoing (NCT04757116).

**Table 2. Summary of Key RCT Characteristics**

Study	Countries	Sites	Dates	Participants <sup>2</sup>	Interventions <sup>1</sup>	
					Active	Comparator
Chughtai et al (2021) <sup>19</sup>	US, Canada	16	2015-2018	Men $\geq 50$ y with IPSS $\geq 10$ , PFR $\leq 12$ mL/s with a 125 mL voided volume, prostate volume 25-75 cc, and normal urinalysis,	iTind device (second generation device, deployed via rigid cytoscope)	Sham (insertion and removal of an 18F silicone Foley catheter)

Study	Countries	Sites	Dates	Participants <sup>2</sup>	Interventions <sup>1</sup>
				CBC, and biochemistry panel. Exclusion criteria included subjects with postvoid residual volume >250 mL, obstructive median lobe, PSA >10 ng/mL or free PSA <25%, previous prostate surgery, prostate or bladder cancer, neurogenic bladder and/or sphincter abnormalities, or 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 $\alpha$ -blockers and 6 months for 5- $\alpha$ -reductase inhibitors. Medication naïve patients were allowed to participate.	(n=128) (n=57)

CBC: complete blood count; IPSS: International Prostate Symptom Score; PFR: peak urinary flow rate; PSA: prostate specific antigen; RCT: randomized controlled trial; UTI: urinary tract infection.

<sup>1</sup> Number randomized; intervention; mode of delivery; dose (frequency/duration).

<sup>2</sup> Key eligibility criteria.

**Table 3. Summary of Key RCT Results**

Study	IPSS $\geq 3$ Response Rate (%)	IPSS (95% CI)	IPSS QoL (95% CI)	Qmax (mL/s) (95% CI)	SHIM/IIEF (95% CI)
Chughtai et al (2021) <sup>19</sup>	N=185	N=185	N=185	N=185	N=185
<b>Change from baseline at 3 months (ITT)</b>					
iTind	78.6%	-9.0	-1.9	4.4	Unchanged
Sham	60.0%	-6.6	-1.5	2.9	Unchanged
<b>MD (95% CI); p</b>	18.6%; p=.029	2.4; p=.063	0.4; p=.264	1.5; p=.230	NR
<b>Change from baseline at 12 months (PP)</b>		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
<b>MD (95% CI); p</b>	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; RCT: randomized controlled trial; SHIM: Sexual Health Inventory for Men.

**Table 4. Study Relevance Limitations**

Study	Population <sup>a</sup>	Intervention <sup>b</sup>	Comparator <sup>c</sup>	Outcomes <sup>d</sup>	Duration of Follow-up <sup>e</sup>
<b>Chughtai et al (2021)<sup>19</sup></b>	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.

<sup>a</sup> 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.

<sup>b</sup> 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.

<sup>c</sup> Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.

<sup>d</sup> 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.

<sup>e</sup> 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 <sup>a</sup>	Blinding <sup>b</sup>	Selective Reporting <sup>c</sup>	Data Completeness <sup>d</sup>	Power <sup>e</sup>	Statistical <sup>f</sup>
<b>Chughtai et al (2021)<sup>19</sup></b>		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.

<sup>a</sup> Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias; 5. Other.

<sup>b</sup> Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.

<sup>c</sup> Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.

<sup>d</sup> 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.

<sup>e</sup> Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.

<sup>f</sup> 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

### 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 3 years.<sup>20,21,22</sup> Study characteristics and results are summarized in Tables 6 and 7. Mean (SD) patient age was 65 (8.9) years with mean 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 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. 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. 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.

### 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.<sup>23</sup> 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
MT-02 (Porpiglia et al [2019]; <sup>20</sup> Kadner et al [2020]; <sup>21</sup> Amparore et al [2021] <sup>22</sup> )	Prospective	Belgium, Italy, Spain, Switzerland, United Kingdom	2014-2020	Men with symptomatic BPH with an IPSS $\geq 10$ , Qmax $\leq 12$ mL/s, and prostate volume $< 75$ mL. Individuals with hemostatic disorders, neurogenic bladder and/or sphincter abnormalities, impaired renal function, history of urethral strictures, post-void residual volume $> 250$ mL, urinary bladder stones, bladder cancer, obstructive median lobe, active UTI, and previous prostate surgery were excluded. Participants were	iTind device (second generation device; deployed under light sedation via rigid cystoscopy) (N=81)	12 months 24 months 36 months



Cohort; Study	Study Type	Country	Dates	Participants	Treatment	Follow-Up
				required to wash-out from BPH-related medications as follows: 1 month for $\alpha$ -blockers and 6 months for 5- $\alpha$ -reductase inhibitors.		
MT-06 (De Nunzio et al [2021] <sup>23</sup> )	Prospective	Australia, France, Germany, Italy, Spain, Switzerland	2018-2019	Men with symptomatic BPH looking to preserve their ejaculatory function with an IPSS $\geq 10$ , Qmax $\leq 12$ 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 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.	iTind device (second generation device; deployed under light sedation via rigid cystoscope)	6 months

BPH: benign prostatic hyperplasia; IPSS: International Prostate Symptom Score; 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
MT-02	N	N	N	N	N
Porpiglia et al (2019); 12 months <sup>20</sup>	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 <sup>21</sup>	51	51	51	51	51
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)

Cohort; Study	Mean Total IPSS	Mean Qmax, mL/s	Mean IPSS - Urinary Symptoms	Mean IPSS QoL	Mean PVR, mL
<b>95% CI; p</b>	-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
<b>Amparore et al (2021); 36 months<sup>22</sup></b>	50	50	50	50	50
<b>Baseline (SD)</b>	20.69 (4.58)	7.71 (2.26)	NR	3.96 (0.87)	68.58 (39.53)
<b>Change (SD)</b>	-12.14 (6.95)	7.49 (6.86)	NR	-2.20 (1.46)	-59.21 (37.75)
<b>95% CI; p</b>	-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
<b>MT-06</b>	N	N	N	N	N
<b>De Nunzio et al (2021); 6 months<sup>23</sup></b>	70	70	70	70	70
<b>Baseline (SD)</b>	NR	7.3 (2.2)	21.2 (6.0)	4.1 (1.0)	69.3 (86.8)
<b>Change (SD)</b>	NR	4.6 (5.5)	-12.7 (6.9)	-2.2 (1.6)	-22.6 (77.3)
<b>95% CI; p</b>	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, IPSS QoL score, 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 prostatic urethral lift 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).<sup>5</sup> These guidelines do not address the use of temporarily implanted nitinol devices.

### 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.<sup>24</sup> 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.

**Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this review are listed in Table 8.

**Table 8. Summary of Key Trials**

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT03395522 <sup>a</sup>	One-arm, Multi-center, International Prospective Study to Assess the Efficacy of Medi-tate Temporary Implantable Nitinol Device (iTind) in Subjects With Symptomatic Benign Prostatic Hyperplasia (BPH) (MT-06)	149	Apr 2025 (ongoing)
NCT04757116 <sup>a</sup>	A Post-Market, Prospective, Randomized, Controlled, Multicenter International Study to Assess the Safety of the Temporarily Implanted Nitinol Device (iTind) Compared to the UroLift® System in Subjects With Symptomatic Benign Prostatic Hyperplasia (BPH) (MT-08)	250	Dec 2025 (recruiting)
<i>Unpublished</i>			
NCT04579913 <sup>a</sup>	A Multi-center, International Prospective Follow up Study to Assess the Safety and Efficacy of the iTind Procedure After Three to Five Years of Follow Up	17	Terminated (COVID-19)

NCT: national clinical trial.

<sup>a</sup> Denotes industry-sponsored or cosponsored trial.

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## Documentation for Clinical Review

- No records required

## Coding

*This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.*

*The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.*

Type	Code	Description
CPT <sup>®</sup>	None	
HCPCS	C9769	Cystourethroscopy, with insertion of temporary prostatic implant/stent with fixation/anchor and incisional struts (Nitinol, iTind device)

## Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
02/01/2023	New policy.

## Definitions of Decision Determinations

**Medically Necessary:** Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

## Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at [www.blueshieldca.com/provider](http://www.blueshieldca.com/provider).

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: [MedPolicy@blueshieldca.com](mailto:MedPolicy@blueshieldca.com)

*Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.*

**Appendix A**

POLICY STATEMENT	
BEFORE	AFTER
<p><b>New Policy</b></p> <p><b>Policy Statement:</b> N/A</p>	<p><b>Temporarily Implanted Nitinol Device (iTind) for Benign Prostatic Hyperplasia 7.01.175</b></p> <p><b>Policy Statement:</b></p> <ol style="list-style-type: none"> <li>I. The use of a temporarily implanted nitinol device (e.g., iTind) is considered <b>investigational</b> as a treatment of lower urinary tract symptoms due to benign prostatic hyperplasia.</li> </ol>