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Temporarily Implanted Prostatic Stents for Benign Prostatic Hyperplasia

Table of Contents

Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

The use of temporary prostatic stents (including implantable nitinol devices e.g., iTind, Spanner®) **is considered experimental, investigational and/or unproven** as a treatment of lower urinary tract symptoms due to benign prostatic hyperplasia**.**

Policy Guidelines

None.

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. Obstruction may occur acutely after surgical treatment for benign

prostatic hyperplasia (BPH), prostatic cancer, or after radiation therapy. Intraprostatic stenting has been investigated as a short-term treatment option, permitting volitional urination as an alternative to the commonly used Foley catheter, in which urine is collected in an external bag. Temporarily implanted stents 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. These devices are 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.

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. Benign prostatic hyperplasia prevalence increases with age and is present in more than 80% of individuals ages 70 to 79 years. (1)

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

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 ≥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 (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). (1) 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. (4) 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." (5) Transurethral resection of the prostate (TURP) is generally considered the reference standard for comparisons of BPH procedures. (6) 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%)." (7) 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. (8) 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. (9) 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). (10) The first-generation TIND device had one extra strut and a pointed tip covered by a soft plastic material.

The Spanner® temporary stent is composed of a proximal balloon to prevent distal displacement, a urine port situated cephalad to the balloon, and a reinforced stent of various lengths to span most of the prostatic urethra. The distal anchor is shaped like a teardrop and positioned in the distal meatus. As the patient voids, the force of the urine compresses the device against the sides of the meatus, thus minimally obstructing the urine flow. A distal anchor mechanism is attached by sutures. Finally, a retrieval suture extends to the meatus and deflates the proximal balloon when pulled. The insertion of this device may be performed as an outpatient/office procedure with or without the use of topical anesthesia.

NOTE: This policy does not address the use of permanent prostatic stents. The Urolume® (AMS, Minneapolis, MN) is an example of a U.S. Food and Drug Administration (FDA)-approved permanent prostatic stent. This wire mesh device is placed into the urethra, where it is slowly incorporated into the urethral wall. This policy only addresses temporary stents, which are designed to be removable.

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 BPH in men age 50 years and older. Product code QKA. (11)

In December 2006, the device "The Spanner®" (SRS Medical, N. Billerica, MA) was approved by the FDA through the premarket approval (PMA) process for temporary use (up to 30 days) to maintain urine flow and allow voluntary urination in patients following minimally invasive treatment for BPH and after initial post-treatment catheterization. Since then, the FDA has approved multiple PMA supplements describing changes to the device's design and manufacturing process. (12)

Rationale

This policy was originally developed in 2005 and has been updated with searches of scientific literature through November 17, 2023. The following is a summary of the key literature to date.

Medical policies 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 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 policy.

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 (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, 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 (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 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) (13)	Ejaculatory function and QOL	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) (14)	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 (15)
American Urological Association Symptom Index (AUASI); International Prostate Symptom Score (IPSS) (1, 3, 16)	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 (16, 1) • Minimum of 30% change (17)
Benign Prostatic Hyperplasia Impact Index (BII) (2)	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 (16)

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) (18), and Porpiglia et al. (2018). (19)

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. (20) 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% confidence interval [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. (21) 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, Ag10 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 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 RCT Characteristics

Study	Countries	Sites	Dates	Participants[2]	Interventions[1]	
					Active	*Comparator*
Chughtai et al. (2021) (21)	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 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, 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.	iTind device (second generation device, deployed via rigid cytoscope) (n=128)	Sham (insertion and removal of an 18F silicone Foley catheter) (n=57)

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

Table 3. Summary of Key RCT 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) (21)	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=.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; RCT: randomized controlled trial; 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) (21)	3. Unclear what proportion of participants was medication naïve.		2. Comparison to an active comparator is of interest. 3. Sham treatment was		1. Not sufficient duration for benefit.

	4. Study racial and ethnic demographics not reported.		administered via silicone Foley catheter versus rigid cytoscope.		

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) (21)		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

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. (22, 23) 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 in 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 retreatment; 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. (24) 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	**MT-02** (Porpiglia et al. [2019], [25] Kadner et al. [2020], [26] Amparore et al. [2021], [22] Amparore et al. [2023] [23])	**MT-06** (De Nunzio et al. [2021] [24])
Study Type	Prospective	Prospective
Country	Belgium, Italy, Spain, Switzerland, United Kingdome	Australia, France, Germany, Italy, Spain, Switzerland
Dates	2014-2020	2018-2019
Participants	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.	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 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.
Treatment	iTind device (second generation device; deployed under light sedation via rigid cystoscope) (N=81)	iTind device (second generation device; deployed under light sedation via rigid cystoscope) (N=70)
Follow-Up	12 months 24 months 36 months >48 months	6 months

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
MT-02	N	N	N	N	N
Poppiglia et al. (2019); 12 months (25)	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 (26)	51	51	51	51	51
Baseline (SD)	20.51 (4.48)	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. (2023); 36 months (22)	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 (23)	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 (24)	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).

Spanner Prostatic Stent

Results from a randomized controlled trial (RCT) by Dineen et al. (27) evaluated the Spanner (Sp) prostatic stent. The study evaluated the impact of the Spanner stent on management of voiding symptoms, irritative symptoms, and outcome after transurethral microwave thermotherapy (TUMT). Patients (n=186) were randomly assigned to the Sp (n=100) or standard of care (SOC, n=86) after TUMT and 3 to 10 days of routine catheterization. After catheter removal, the SOC group received no further treatment until follow-up visits. Primary outcomes evaluated included the International Prostate Symptom Score (IPSS) voiding subscore, IPSS irritative subscore, voiding diary data, and Benign Prostatic Hyperplasia Impact Index 7 to 10 days before TUMT and repeated 1, 2, 4 (stent removal), 5, and 8 weeks after stent insertion. The IPSS voiding and irritative subscores showed statistically significant improvement at week 1 for the Sp group but no significant differences at weeks 2, 4, 5, and 8. For the individual IPSS voiding and irritative questions of incomplete emptying, there were no significant differences between the Sp and SOC groups at any visit. Overall, individual IPSS irritative questions did not differ significantly between the Sp and SOC groups at 1, 2, and 4 weeks after stent insertion. From the voiding diary data, the feeling of incomplete emptying, terminal dribble, and leakage were not significantly different between the Sp and SOC groups at any visit. On the Benign

Prostatic Hyperplasia Impact Index, the Sp group was less bothered during the time of stent use (2 weeks). The remaining weeks for this index were similar in both groups. While this study showed statistically significant changes in some outcome measures, the study has a number of limitations. First, participants or practitioners were not blinded to the treatment, so potential biases could have occurred on reporting the outcome measures. Second, no information is given about dropout rates or missing data. Finally, the clinical significance of many of the findings is not known. Thus, these data are inconclusive regarding the role of temporary prostatic stents for prostatic obstruction conditions.

Another report on the Spanner stent, published in 2007, described repeated temporary stent use in 43 consecutive patients with bladder-outlet obstruction who were unfit for surgery. (28) It was reported that more than half of the patients (63%) had unsatisfactory outcomes; the remaining 37% were considered to have had satisfactory outcomes, either with a stent in situ after a mean of 5 changes or stent-free after a successful voiding trial.

In 2006, Kijvikai and colleagues conducted a study in Europe to assess the efficacy and safety of 2 versions of a blind placement temporary prostatic stent (BPS-1 and BPS-2) in the treatment of patients with benign prostatic obstruction. (29) A total of 55 men were enrolled in the trial. Spontaneous voiding was achieved in all patients immediately after stent insertion, with improvements in voiding parameters and symptom scores. In patients with the BPS-1, migration occurred in 85%. In patients with the BPS-2, migration occurred in 5%. The median indwelling time of the stent was 16 days for the BPS-1 and 38 days for the BPS-2. Removal was successful in all but 1 case (BPS-2). The authors concluded that the BPS-1 and BPS-2 are not suitable for clinical practice because of the significantly high migration rate (BPS-1) and voiding parameters and symptom scores (BPS-2) that were not significantly improved. Given the study location and lack of U.S. Food and Drug Administration (FDA) approval for these devices, these data are insufficient to draw conclusions regarding the use of these devices.

In 2005 and 2006, van Dijk and colleagues conducted studies for 2 designs (hourglass-shaped and bell-shaped) of removable stents in a total of 143 subjects. (30, 31) Unsatisfactory outcomes were reported for both models; the stents required early removal due to migration and other sources of pain, with a median retention of less than 105 days.

In 2008, Vanderbrink and colleagues published a review of the use of the temporary prostatic stent. (32) The report concluded that "…. a major disadvantage of temporary prostatic stents is that they have a small lumen that can result in urinary retention secondary to clot–induced impairment of catheter patency, when placed in the immediate post-TUMT treatment."

ECRI Institute

In April 2018 ECRI released a Product Brief titled: Spanner Prostatic Stent (SRS Medical) for Maintaining Urine Flow after Treatment for Benign Prostatic Hyperplasia (33).

ECRI searched PubMed, EMBASE, and selected web-based resources for documents relevant to this topic and published between January 1, 2000 and April 11, 2018. Full-text of 1 RCT and the

abstract of 1 retrospective case series were reviewed; studies reported on 211 patients. Also reviewed was a published abstract that reported additional outcomes of the RCT.

The authors of this product brief noted that the studies provide some evidence suggesting that Spanner may be safe and effective for temporary LUTS relief after BPH thermotherapy. A multicenter RCT (n = 186) (34) used two validated questionnaires to compare urinary symptoms in patients treated with Spanner placement or standard medical therapy for one month following TUMT and successful Foley catheter removal. Patients in the Spanner group reported better overall scores during treatment and reported large symptom relief more often than patients in the control group (44% versus 28% of patients). In addition, patients reported better irritative symptom and QOL IPSS subscores one month after Spanner removal; suggesting that Spanner results in durable benefits. Patients experienced similar rates of serious AEs in both groups. The most common serious adverse events (AEs) with Spanner included urinary tract infection (15% of patients), urinary retention (6%), and stent migration (5%).

A smaller, retrospective case series (n = 25) (35) reported no serious adverse events at Spanner removal in patients who had the device for 2 to 28 days (mean 16). Patients and physicians reported high rates of satisfaction (79% to 87%) with the device in the RCT.

Both studies also reported on urinary flow parameters such as peak flow rate post-voiding residual volume. However, ECRI did not consider these findings in their assessment because flow metrics are surrogate outcomes that do not clearly predict patient-centered outcomes. Although urinary dysfunction generally results in flow metric changes, individual perception of these changes varies greatly; and clinical experts do not agree on the clinical value of urinary flow metrics. ECRI noted: “That while favorable, the evidence on Spanner is of insufficient quantity and quality to support conclusions. A multicenter RCT assessed patient-reported LUTS relief with Spanner. However, findings are at risk of bias because blinding patients to Spanner placement is not possible. Independent confirmation of findings in additional RCTs is needed for data to be conclusive. Safety outcomes are at low risk of bias in the RCT, but a single small case series provides insufficient validation. Thus, additional studies of safety are needed. Furthermore, a significant evidence gap remains. No data are available to compare Spanner with alternative interventions such as indwelling Foley catheters and intermittent self-catheterization. Reviewed findings pertain only to TUMT and may not fully generalize to other interventions such as visual laser ablation of the prostate (VLAP) or interstitial laser coagulation of the prostate (ILC). Studies that address these gaps are needed to assess Spanner’s clinical utility.”

ECRI’s executive summary noted: “Very limited evidence from 1 RCT and 1 case series suggests that Spanner may be safe and relieve LUTS in patients who undergo TUMT. However, findings are at high risk of bias and additional studies are needed to confirm results and compare Spanner with indwelling Foley catheters, intermittent self-catheterization, and to validate use with other thermotherapy procedures. An ongoing study will not provide data to address evidence gaps.”

Practice Guidelines and Position Statements

American Urological Association (AUA)

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. (36) This recommendation was based on expert opinion due to an absence of sufficient evidence.

Canadian Urological Association (CUA)

In a 2022 guideline, the CUA recommended that temporary stents have a limited role in treatment of moderate to severe lower urinary tract symptoms (LUTS). A newer generation of stents are currently being evaluated and may provide an alternative surgical option for the management of BPH LUTS in the future. (37)

National Institute for Health and Care Excellence (NICE)

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. (38) 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.

Summary of Evidence

For individuals who have benign prostatic hyperplasia (BPH) with lower urinary tract symptoms who receive a temporary prostatic stent (e.g., iTIND or Spanner) the evidence includes a meta-analysis, randomized controlled trials (RCT's), a case series for Spanner 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. One Spanner study

looked at 43 patients with bladder-outlet obstruction who were unfit for surgery. It was reported that more than half of the patients (63%) had unsatisfactory outcomes. Another RCT on studied the impact of the Spanner stent on management of voiding symptoms, irritative symptoms, and outcome after transurethral microwave thermotherapy (TUMT). The IPSS voiding and irritative subscores showed statistically significant improvement at week 1 for the Sp group but no significant differences at weeks 2, 4, 5, and 8. For the individual IPSS voiding and irritative questions of incomplete emptying, there were no significant differences between the Sp and SOC groups at any visit. Overall, available data was inconclusive regarding the role of temporary prostatic stents for prostatic obstructive conditions. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in Table 8.

Table 8. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03395522[a]	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[a]	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)
Unpublished			
NCT04579913[a]	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; No: number.

[a]Denotes industry-sponsored or cosponsored trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	53855
HCPCS Codes	C9769

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Centers for Medicare and Medicaid Services (CMS)

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A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision	
Date	**Description of Change**
07/15/2024	Document updated with literature review. Coverage unchanged. References 1-10, 12-17, 20, 23-24, 36 and 38 added; others removed. Title changed from Temporary Prostatic Stent.
07/01/2023	Reviewed. No changes.
01/01/2023	Document updated with literature review. Coverage unchanged. References 14 and 15 added; others updated.
01/01/2022	Reviewed. No changes.
10/01/2020	Document updated with literature review. The following change was made to Coverage: Added "(including implantable nitinol devices)". Added references 1, 2, 9-13, and 19.
09/15/2020	Document updated with literature review. Coverage unchanged. Reference 11 added; others removed.
11/15/2019	Reviewed. No changes.
06/15/2018	Document updated with literature review. Coverage unchanged. References 10-12 added.
07/15/2017	Document updated with literature review. Coverage unchanged.
03/15/2016	Reviewed. No changes.
04/15/2015	Document updated with literature review. Coverage unchanged.
10/15/2013	Document updated with literature review. Coverage unchanged. Description and Rationale completely revised.
06/01/2008	Policy reviewed without literature review; new review date only. This policy is no longer scheduled for routine literature review and update.
09/15/2007	Revised/updated entire document
09/01/2005	New medical document