Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 1/1/25**
(See policy history boxes for previous effective dates)

Title: Temporarily Implanted Prostatic Devices for Benign Prostatic Hyperplasia (e.g., Nitinol [iTIND], Spanner™)

Description/Background

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. 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 aged 70 to 79 years.(1)

Temporarily implanted 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.

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)

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 as an outpatient procedure with the patient under topical anesthesia or as an office procedure without anesthesia.

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 and older. Product Code: QKA

In October 2022, The Spanner™ Temporary Prostatic Stent (SRS Medical Systems, Inc., North Billerica MA) expansion request was approved by the FDA through the premarket approval process for temporary use (up to 30 days) to maintain urine flow and allow voluntary urination for patients who are not candidates for pharmacologic, minimally invasive or surgical treatment of the prostate. Product code: NZC

Medical Policy Statement

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

Placement of temporary prostatic stents (e.g., Spanner™) is experimental/investigational for all uses, including, but not limited to BPH, following surgical treatment of BPH, prostate cancer or radiation therapy. They have not been scientifically demonstrated to be as safe and effective as conventional treatment and have not been shown to improve net health outcomes.

Inclusionary and Exclusionary Guidelines **(Clinically based guidelines that may support individual consideration and pre-authorization decisions)**

N/A

CPT/HCPCS Level II Codes ***(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)***

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

C9769 53855

Note: Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.

Rationale

Temporarily Implanted Prostatic Devices

Clinical Context and Therapy Purpose
The purpose of temporarily implanted 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 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) and other temporary devices (e.g., Spanner).

- 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.
- The Spanner Temporary Prostatic 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.

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 to5. 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)[11,]	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)[12,]	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[13,]
American Urological Association Symptom Index (AUASI); International Prostate Symptom Score (IPSS)[1,3,14,]	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[14,1,] • Minimum of 30% change[15,]
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[14,]

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)(16) and Porpiglia et al (2018).(17)

Review of Evidence

Nitinol Devices

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.(18) 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 (BPH).(19) 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 prostatic urethral lift (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)[19.]	US, Canada	16	2015-2018	Men ≥ 50 y 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 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 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; RCT: randomized controlled trial; UTI: urinary tract infection.
[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)[19.]	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; 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)[19]	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)[19]		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 >4 years.(20-21) 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, 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.(22) 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]; Kadner et al [2020]; Amparore 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	iTind device (second generation device; deployed under light	12 months 24 months 36 months

				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 required to wash-out from BPH-related medications as follows: 1 month for α-blockers and 6 months for 5-α-reductase inhibitors.	sedation via rigid cystoscope) (N=81)	>48 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 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	iTind device (second generation device; deployed under light sedation via rigid cystoscope) (N=70)	6 months

			drug therapy after device retrieval.		

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	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
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 procedure is ongoing (NCT04757116).

Temporarily Implanted Prostatic Stents (e.g., Spanner)
The Spanner (The SPANNER, AbbeyMoor Medical, Inc., Parkers Prairie, MN, USA) is a temporary silicone elastomer prostatic stent which has received FDA approval. It is inserted into the urethra at the neck of the bladder. The Spanner's proximal balloon is seated in the bladder neck, and the stent extends from the bladder neck to just above the external sphincter. It has a tethering device (suture material) that transverses the external sphincter and allows for normal sphincteric function. A distal anchor in the bulbar urethra (just below the sphincter) prevents device movement and migration into the bladder.

Peyton et al (2015) reviewed the past and present literature on the clinical utility and efficacy of prostatic stents in the treatment of benign prostatic obstruction. Findings indicate that permanent stents have largely been abandoned in North America due to unfavorable outcomes and improved technologies. The Spanner stent effectiveness was primarily documented for temporary relief of tissue edema following minimal invasive ablative treatments, however adequate detrusor function was required and irritative symptoms were an issue. Literature was found lacking regarding assessments of bladder function for many of the clinical studies for prostatic stents. It was pointed out that prostatic stents may not help men with a lack of bladder contractility. Authors concluded that further development is needed to design an ideal prostatic stent.

Goh et al (2013) assessed the ease of insertion and removal of the Spanner^{TM} stent in 16 individuals. All insertions were uncomplicated. The stents stayed in situ for a median of 10 days. Twelve stents were removed prematurely due to severe symptoms or retention. A total of 12 stents had to be removed endoscopically as removal via the retrieval suture was unsuccessful. Authors determined that possible causes of stent failure included underestimation of the prostatic urethral length (leading to obstruction by apical prostatic tissue), excessive suture length between the stent and the distal anchor (permitting proximal migration), and inadequate suture length (leading to urinary incontinence). Further design modifications were recommended.

Cerrato et al (2024) performed a systematic search of literature which involved (1) all age groups,(2) individuals with BPH treated with a prostatic stent, and (3) all available stents. Four studies were noted which reviewed the use of the Spanner stent. One study (n=30) with 12 week follow-up demonstrated a 42% enhancement in the mean Qmax, a 64% decrease in PVR, and a 68% decrease in IPSS with a remarkable lack of migration on radiological confirmation (0%). Subjects reported increased sexual activity and erections without significant pain. In another observational study (n=43) the stent was replaced every 3 months with an overall 63% of the subjects experiencing an unsatisfactory outcome due to immediate or delayed urinary retention or elective stent removal caused by severe symptoms. In a multicenter RCT, an 86% subject satisfaction rate and better QoL with the Spanner stent was

reported, along with improvement in PVR, uroflowmetry and IPSS over an 8-week follow-up when compared to the standard foley catheter following transurethral microwave thermotherapy for chronic obstruction due to BPH. Finally, the study that lead to FDA approval determined that after 3 cycles of 30 days, 73.8% of subjects maintained a PVR $\leq$ 150ml, and did not report any device-related serious adverse events. Most adverse events were asymptomatic bacteriuria (23.4%), pain (9.4%) and urinary urgency (7.5%). Overall authors concluded that although prostatic stents seem to be promising in terms of effectiveness and safety while improving individual QoL and IPSS, more long-term data are needed to further titrate and identify the individuals who are most suitable and likely to benefit the most from prostatic stents.

Section Summary: Temporarily Implanted Prostatic Stents
There is insufficient evidence in the peer-reviewed medical literature to establish the role of temporarily implanted prostatic stents in benign prostatic hyperplasia. Published data comparing temporarily implanted prostatic stents with the gold standard are lacking. There were no studies identified which determine that this modality improves health outcomes.

Summary of Evidence
For individuals who have benign prostatic hyperplasia (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, and treatment-related morbidity. One network meta-analysis compared the safety and efficacy of various minimally-invasive treatments for lower urinary tract symptoms associated with BPH, finding that iTind may result in worse urologic symptoms scores compared to TURP at short-term follow-up. One RCT compared the iTind device with a sham procedure and reported an improvement of at least 3 points on the IPSS scale at 3 months in 78.6% versus 60% of participants, respectively (p=.029). However, corresponding changes in overall IPSS, IPSS QoL, Qmax, SHIM, and IIEF scores were not significantly different between groups. One single-arm study reported significant improvements in symptoms and functional outcomes through >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 MSHQ-EjD questionnaire at 6 months. No studies have directly compared iTind to established alternatives; however, an RCT comparing iTind with the UroLift prostratic urethral lift procedure is currently ongoing. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have benign prostatic hyperplasia and receive temporary implanted prostatic stents, well designed clinical trials supporting efficacy are lacking. There were no guidelines identified which support the use of temporary prostatic stents. There is insufficient evidence in the peer reviewed medical literature regarding how the use of temporary prostatic stents would directly improve health outcomes in relation to the gold standard. 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 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
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.
[a] Denotes industry-sponsored or cosponsored trial.

Supplemental Information

American Urological Association

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

A 2023 amendment to the 2021 AUA guideline stated that temporary implanted prostatic devices are an option for individuals with BPH, LUTS, prostate volume of 25 to 75 grams, and who lack an obstructive median lobe.(25) This recommendation was based on “expert opinion” due to an absence of sufficient evidence. All other devices approved for LUTS/BPH in this guideline have at least a “C” recommendation.

National Institute for Health and Care Excellence

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

Government Regulations

National:

No determination found.

Local:

No determination found.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated

and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Aquablation of the Prostate
- Prostatic artery embolization (PAE) for BPH
- Prostatic Urethral Lift Procedure

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 8/2/24, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
8/26/05	8/26/05	9/8/05	Joint policy established
9/1/08	7/25/08	9/1/08	Routine maintenance
9/1/10	6/15/10	6/15/10	Code update; deleted code 0084T, added 53855. No change in status.
1/1/13	10/16/12	10/16/12	Policy updated to mirror BCBSA. Title changed from "Temporary Prostatic Urethral Stents" to "Temporary Prostatic Stent".
7/1/14	4/10/14	4/15/14	Routine maintenance
9/1/15	6/19/15	7/16/15	Routine maintenance
9/1/16	6/21/16	6/21/16	Routine maintenance; policy retired
1/1/24	10/17/23		• BCBSM policy unretired (slp) • Title changed from "Temporary prostatic stent" • Vendor: N/A • Incorporated IMP - Temporary Prostatic Urethral Stent Usage (including implantable nitinol devices)
1/1/25	10/15/24		• Routine maintenance (slp) • Vendor managed: N/A • Policy title changed from: "Temporarily Implanted Prostatic Stents for Benign Prostatic Hyperplasia (e.g., Nitinol Device [iTind])" to: "Temporarily Implanted Prostatic Devices for Benign Prostatic Hyperplasia (e.g., Nitinol [iTind], Spanner™)"

Next Review Date: 4th Qtr, 2025

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: TEMPORARILY IMPLANTED PROSTATIC DEVICES FOR BENIGN PROSTATIC HYPERPLASIA (E.G., NITINOL [ITIND], SPANNER™)

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	Refer to the Medicare information under the Government Regulations section of this policy.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.
- Duplicate (back-up) equipment is not a covered benefit.