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Medical Policy Manual Surgery, Policy No. 230

Devices for Treatment of Benign Prostatic Hyperplasia, Urethral Stricture, and Urethral Stenosis

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Temporarily implanted nitinol devices (e.g., iTind) have been proposed as a minimally invasive alternative to transurethral resection of the prostate (TURP) to treat 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 five to seven days.

Drug-coated balloon catheter systems (e.g., Optilume®) have been proposed as minimally invasive alternatives to TURP, endoscopic management, and urethroplasty to treat obstructive urinary tract symptoms associated with benign prostatic hyperplasia or urethral stricture. The devices utilize balloon catheters to dilate the urethra or prostate lobes and deliver paclitaxel indicated to prevent future obstructive urinary symptoms.

Prostatic urethral scaffold devices (e.g., Zenflow Spring®) have been proposed as a minimally invasive surgical therapy for benign prostatic hyperplasia. The urethral scaffold or “spring” nitinol device treats urinary obstruction by maintaining the patency of the urethra within the prostate. The device is placed using minimally invasive surgery and is designed to be permanent.

MEDICAL POLICY CRITERIA

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

II. The use of a drug-coated balloon catheter system (e.g., Optilume® BPH Catheter System) is considered **investigational** for all indications, including treatment of obstructive urinary symptoms associated with benign prostatic hyperplasia.

III. The use of a drug-coated balloon catheter system (e.g., Optilume® Urethral Drug Coated Balloon) is considered **investigational** for all indications, including treatment of obstructive urinary symptoms associated with anterior urethral stricture.

IV. Use of a prostatic urethral scaffold (e.g., Zenflow Spring® System) is considered **investigational** for all indications, including treatment of symptoms due to benign prostatic hyperplasia.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. Transurethral Water Vapor Thermal Therapy and Transurethral Water Jet Ablation (Aquablation) of the Prostate, Surgery Policy No. 210

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. BPH prevalence increases with age and is present in more than 80% of individuals age 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 seven-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). 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 (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 one year and by more than 45% over four 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 (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 cystoscope, the device is temporarily implanted into the obstructed prostatic urethra where three 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 five to seven 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 French units [Fr]).[10] The first-generation TIND device had one extra strut and a pointed tip covered by a soft plastic material.

The Optilume® BPH Catheter System is a drug and device combination that consists of two catheters: a non-drug coated catheter for pre-dilation (Optilume® BPH Prostatic Pre-dilation Catheter) and a paclitaxel coated catheter (Optilume® BPH Prostatic Dilation Drug Coated Balloon Catheter).[11] The Pre-dilation Catheter is used to initiate a commissurotomy between the lateral lobes of the prostate. The Drug Coated Balloon Catheter further dilates and completes the commissurotomy then transfers paclitaxel to the pre-dilated prostatic urethra and anterior commissure. The increase in cross-sectional area of the prostatic urethra from the anterior commissurotomy permits increased urine flow. Transfer of the paclitaxel from the balloon surface to the dilated area inhibits cell proliferation and maintains urethral patency.

URETHRAL STRICTURE AND STENOSIS

Urethral stricture is the chronic fibrosis and narrowing of the urethral lumen caused by acute injury, inflammatory conditions, and interventions including urethral instrumentation, surgery, and prostate cancer treatment.[12] Urethral stricture is the preferred term for abnormal narrowing of the anterior urethra, and narrowing of the posterior urethra is referred to as stenosis. Urethral stricture symptoms are often non-specific and overlap with other common conditions including LUTS and UTI. Patients with urethral stricture most often present with decreased urinary stream and incomplete bladder emptying but may also have UTI, epididymitis, rising post-void residual, decreased ejaculation force, urinary spraying, or dysuria. In high income countries, the most common cause of urethral stricture is idiopathic (41%) followed by medical treatments (35%). In low- and middle-income countries, trauma is the most common cause of urethral stricture (36%).

Initial management of urethral stricture includes assessing patient medical history, physical examination, and urinalysis.[12] A combination of patient reported measures, uroflowmetry, and ultrasound post-void residual assessment are recommended for initial evaluation of suspected urethral stricture. Urethro-cystoscopy, retrograde urethrography, voiding cystourethrography, or ultrasound urethrography are recommended for diagnosis of urethral stricture. For urgent management of urethral stricture, urethral endoscopic management (e.g., urethral dilation, direct visual internal urethrotomy [DVIU]) or immediate suprapubic cystostomy are recommended. For non-urgent strictures, the length and location of the stricture should be determined to guide treatment. For initial treatment of short (less than two centimeters [cm]) bulbar urethral strictures, urethral dilation, DVIU, or urethroplasty are recommended.

Urethroplasty, instead of repeated endoscopic management, is recommended for management of recurrent anterior urethral strictures following failed dilation or DVIU. Urethral dilation and DVIU are also recommended for recurrent bulbar urethral strictures that are less than three cm in length. Urethral dilation and DVIU have similar long-term outcomes, with success ranging from 35-70% for short strictures. These endoscopic treatments have high success rates for strictures less than one cm but very low success rates for strictures over two cm. Urethroplasty has a higher long-term success rate than endoscopic treatment (80-95%), but American Urological Association (AUA) guidelines recommend weighing success against the increased anesthesia requirement and higher morbidity of urethroplasty.

The Optilume® Urethral Drug Coated Balloon is a 0.97 mm over-the-wire guidewire compatible catheter with a dual lumen design and a tapered, atraumatic tip.[13] The Optilume® Drug Coated Balloon is used to exert radial force to dilate narrow urethral strictures. Using a guidewire, the catheter is inserted into the area of the urethra that has a stricture, and the balloon is inflated to mechanically dilate the urethra and improve urine flow. During balloon inflation, paclitaxel is transferred from the balloon to the urethra to prevent stricture recurrence.

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).[14] 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 years and older.

In September 2021, the Optilume® Urethral Drug Coated Balloon (Urotronic, Inc.) received premarket approval from the U.S. FDA (P210020, product code: QRH).[13] The Optilume®

Urethral Drug Coated Balloon is indicated for the treatment of obstructive urinary symptoms associated with anterior urethral stricture in adult males with urethral stricture less than or equal to three cm in length.

In June 2023, the Optilume® BPH Catheter System (Urotronic, Inc.) received premarket approval by the U.S. FDA (P220029; product code: QXB).[11] The Optilume® BPH Catheter System is indicated for the treatment of obstructive urinary symptoms associated with BPH in males age 50 years and older.

As of November, 2024 the Zenflow Spring® System is an investigational device and not FDA approved.[15]

EVIDENCE SUMMARY

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 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).

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)[16]	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)[17]	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[18]
American Urological Association Symptom Index (AUASI);	Severity of lower urinary tract symptoms	Patient-administered, 7-item scale. Symptoms rated as mild (0-7),	• Minimum of 3-point change[1, 19]

Measure	Outcome Evaluated	Description	Clinically Meaningful Difference (If Known)
International Prostate Symptom Score (IPSS)[1, 3, 19]		moderate (8-19), or severe (20-35). IPSS asks an additional question, rating QOL as delighted (0) to terrible (6).	• Minimum of 30% change[20]
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[19]

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 Bertolo (2015)[21] and Porpiglia (2018).[22]

Review of Evidence

Systematic Reviews

Baboudjian (2023) conducted a systematic review of pharmacologic and surgical retreatment rates after water vapor thermal therapy (WVTT), prostatic urethral lift (PUL), and iTind procedures.[23] The review included 36 studies involving 6380 patients. Three studies, including one RCT, reported on 288 participants who were treated with iTind. The maximum follow-up in the iTind studies was three years. At one year, iTind had the lowest rate of surgical retreatment (2% vs. 3% for WVTT and 6% for PUL). At three years, the surgical retreatment rate for iTind was 5%. Five-year rates were available for WVTT (4%) and PUL (13%), however, the difference was not significant. At one year, 3% of the iTind group, 3% of the WVTT group, and 1% of the PUL group had pharmacologic retreatment. At maximum follow-up (three years for iTind) the retreatment rate was 7% for iTind, and at five years was 11% for WVTT and PUL. A lack of documentation of pharmacologic data was noted. The authors also note the studies included highly selected participants so may not be representative of all people with BPH. The

authors concluded that rates of surgical retreatment between the therapies are similar but more data is needed to understand pharmacologic treatment rates.

In 2021, Franco published a Cochrane network meta-analysis assessing the comparative effectiveness of minimally invasive treatments for lower urinary tract symptoms in men with BPH.[24] 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 (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.[25] 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 three points on the IPSS scale at three 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<0.001). While a significantly higher proportion of patients treated with iTind achieved the primary endpoint compared to sham at three months (78.6% vs. 60%; p=.029), changes in overall IPSS, IPSS QoL, Qmax, SHIM, and International Index of Erectile Function (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 two events in two subjects in the sham group. In the iTind group, a total of five 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 six participants (4.7%) resumed medication for symptomatic BPH. An RCT comparing the iTind device to the UroLift prostatic urethral lift (PUL) procedure is ongoing (NCT04757116).

Using questionnaire data from the Chughtai (2021)[25] study, Elterman (2023)[26] reported the effect of iTind on sexual function. Patient-reported sexual health data from subjects who completed study visits at 3 and 12 months, and who were not taking medication to treat BPH were included. Using primarily SHIM scores, the study found no evidence of decrease in sexual function due to iTind at 12 months. Limitations of the study include that the total number of study subjects that provided data and the n-values of the subgroups (stratified by age, prostate volume, and questionnaire scores) were not specified. Another major limitation was that the 12-month comparison was between baseline and 12-month scores within the iTind treatment arm, with no comparison between the iTind treatment and the sham treatment at 12-months.

Single-Arm Studies

MT-02 Cohort

81 subjects with lower urinary tract symptoms due to BPH were implanted with the second-generation iTind device and followed for up to three years.[27-29] Mean (SD) patient age was 65 (8.9) years with mean prostate volume 40.5 (12.25) milliliter (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, two-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 seven were later found to have obstructive median lobes (p<.0001). Subsequent drug therapy was required in five (6.2%) patients and eight (8.6%) underwent surgical retreatment via TURP or laser. Sexually active patients who completed a two-item questionnaire reported no sexual or ejaculatory dysfunction through three years.

Amparore (2023) reported >48 months follow-up of the MT02 cohort. The participants were assessed via telephone once during the 50-79 months postoperative period for IPSS and IPSS-QoL, change in medication, need for surgical re-treatment, and adverse events.[30] Three centers agreed to continue follow-up >48 months. Out of 50 participants 5 were lost to follow-up and two died from causes unrelated to the ITind device. Two participants required surgical retreatment. For the remaining 41 participants (50.6% of the cohort) at a mean follow-up time of 60.2 months IPSS increased +2.7 points since the 36-month follow-up, which was a 11.26+/-7.67 improvement from baseline. IPSS-QoL showed an increase of 2.10+/-1.41 points with an improvement from baseline of -45.1%. Both values were a significant improvement from baseline (p<0.0001). No patients restarted oral medications and no late adverse events were recorded beyond 48 months of follow-up. From baseline a total of 11.1% of participants have required surgical retreatment. The authors concluded iTind is effective and safe; however, the study is limited by lack of comparison of iTind to either other therapy or sham treatment.

MT-06 Cohort

De Nunzio (2021) reported six-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.[31] 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 six 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 three years.

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 three 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 six months. One RCT comparing the iTind device to sham treatment reported an improvement of at least three points on the IPSS scale at three 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. A follow-up study reported no evidence of decrease in sexual function at 12 months due to iTind, but evidence was limited by lack of comparison between the treatment arms. 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. No studies have directly compared iTind to established alternatives. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

OPTILUME® BPH CATHETER SYSTEM

Clinical Context and Therapy Purpose

Use of a drug-coated balloon catheter system in patients who have obstructive urinary symptoms associated with BPH is to provide a treatment alternative to, or an improvement on, existing therapies such as pharmacological therapies, prostate ablation (e.g., laser, vapor), PUL, prostatectomy, or TURP.

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.

Randomized Controlled Trials

Kaplan (2023) published results of the PINNACLE double-blind, sham-controlled, multi-center RCT that assessed the Optilume® BPH Catheter System. 148 male participants 50 years or older, with symptomatic BPH and a prostate size between 20 and 80 grams, were randomized to receive the active treatment (n=100) or sham treatment (n=48). Sham treatment consisted of rigid cystoscopy followed by insertion of a sheathed (21F) Optilume® BPH Predilation Catheter that was not inflated. The timing, analgesia, and anesthesia protocols were the same in active and sham treatment groups. Participants and evaluators were blinded through one-year follow-up. Average improvement in IPSS from baseline to one year was significantly greater with active treatment (11.5±7.8) than sham treatment at three months (8.0±8.3), with an estimated difference of 3.4 between groups (95% CI, 0.6 to 6.2; p=0.008). However, this result was not significant when a 25% super-superiority margin was used (p=0.18). IPSS improved on average by 49% from baseline to one year in the active treatment group (95% CI, 42.7% to 55.4%), which met the prespecified performance goal of 30% (p<0.001). Significantly more participants experienced at least a 30% improvement in IPSS at one year when compared to the sham group at three months (76.6% [66 of 96] versus 52.1% [25 of 48], p=0.003). The change in Qmax from baseline also significantly favored Optilume® BPH at 12 months over sham at three months (+9.7±10.1 versus +5.5±7.4 mL/s, p=0.009). Five serious treatment-related events occurred. Four post-procedural hematuria events that required

cystoscopic management or extended observation, which resolved without sequelae, occurred. One event of urethral false passage required extended catheterization. Common nonserious adverse events that occurred in the Optilume® BPH arm, regardless of relatedness, included hematuria (40% [39 of 98]), urinary tract infection (14% [14 of 98], dysuria (9.2% [9 of 98]), urge/mixed incontinence (8.2% [8 of 98]), mild stress incontinence (7.1% [7 of 98]), bladder spasms (6.1% [6 of 98]), elevated PSA (6.1% [6 of 98]), and urinary urgency (6.1% [6 of 98]). This study is limited by different follow-up times for the Optilume BPH and sham treatment groups and eligibility criteria were limited to men with prostates below 80 grams.

Single-Arm Studies

Kaplan (2021) published one-year outcomes of the EVEREST-I single-arm study that evaluated the safety and efficacy of the Optilume® BPH Catheter System. Participants were greater than 50 years old with moderate to severe LUTS secondary to BPH, peak urinary flow rate of 5 to 15 mL/s, prostatic urethra length 30 to 55 millimeters, and prostate volume 20 to 80 grams (n=80). After treatment, participants were followed up at time of Foley catheter removal, two weeks, 30 days, and 3, 6, and 12 months after treatment. The primary endpoint was the proportion of subjects with greater than or equal to 40% improvement in IPSS. 75 participants completed the one-year follow-up. At three months and one year, 81% of participants experienced greater than or equal to 40% improvement in IPSS from baseline (90% CI, 72.6 to 88.1). Mean IPSS was 22.3 at baseline and 7.9 at one year. Qmax improved from 10.9 to 18.4 mL/s, and IPSS-measured quality of life improved from 4.6 to 1.3 at one-year follow-up. 113 adverse events were reported. The most frequent treatment-related adverse events were post-procedural hematuria (15.0%), postoperative urinary retention (13.8%), urinary incontinence (13.8%), urinary tract infection (8.8%), ejaculation disorder (8.8%), and dysuria (7.5%). Most postoperative urinary retention events were caused by clots blocking the Foley catheter outlet, and greater than 90% (11 of 12) events resolved within one week. Interim data analysis revealed a worse safety profile with use of the large diameter balloon catheter, including higher rates of bleeding and incontinence. As a result, this device size option was removed for the last 31 participants treated in the study. This study is limited by lack of a control group, and longer-term follow-up is necessary to determine treatment durability.

Section Summary: Optilume® BPH Catheter System

Data from one RCT and one single-arm study suggest that the Optilume® BPH Catheter System may improve peak urinary flow rate and symptoms associated with benign prostatic hyperplasia, but symptom scores did not reach statistical significance in the RCT. There are multiple limitations of the data including lack of control group in one study, concerns about serious adverse events (hematuria was most common), and the treatment may not be generalizable for prostates above 80g. Long-term follow-up is also needed to determine durability of this treatment. No studies have directly compared the Optilume® BPH Catheter System to established treatments. There is also a lack of data on paclitaxel in tissues at long-term follow-up. There is not yet enough evidence that the technology results in an improvement in the net health outcome.

OPTILUME® DRUG COATED URETHRAL DILATION CATHETER

Clinical Context and Therapy Purpose

Use of a drug-coated urethral dilation catheter in male patients who have obstructive urinary symptoms associated with anterior urethral stricture is to provide a treatment alternative to, or an improvement on, existing therapies such as urethral dilation with an uncoated balloon catheter, endoscopic management or urethroplasty. Relevant outcomes include patient-reported measures such as the AUASI and IPSS to assess symptoms, uroflowmetry to determine severity of obstruction, and evaluation of stricture diameter with urethroscopy, retrograde urethrography, or ultrasound urethrography.

Randomized Controlled Trials

Elliot (2022) published one-year outcomes from the ROBUST III multi-center, single-blind trial that evaluated the safety and efficacy of the Optilume® DCB for treatment of recurrent anterior urethral strictures.[32] Participants were adult males with anterior urethral strictures less than or equal to 12Fr in diameter and less than or equal to three cm long, who had at least two prior endoscopic treatments, IPSS score greater than or equal to 11, and maximum urine flow rate less than 15 mL per second. The primary efficacy endpoint was anatomical success, defined as diameter greater than or equal to 14Fr determined by urethral cystoscopy or calibration at six months. 127 participants were randomized 2:1 to treatment and control groups and were blinded to treatment through six months. Endoscopic control treatments were the standard of care at each site and included treatment with an uncoated balloon catheter, direct visual internal urethrotomy (DVIU), serial diltion with urethral sounds, or a combination of these treatments. Post-procedure follow-up occurred at Foley catheter removal (two to five days in both groups), 30 days, three months, six months, and one year. At six months, anatomical success was 75.6% in the DCB group and 26.8% in the control group, with an estimated difference of 44.4% ($p<0.0001$). Freedom from repeat intervention through one year was significantly higher for the DCB group than the control group (83.2% versus 21.7%, $p<0.0001$). From baseline to 30 days, both groups experienced a significant increase in Qmax, IPSS, and IPSS quality of life scores. However, the control group experienced deterioration in all of these categories by one year while the significant improvements remained at one year in the DCB group. Adverse event types and rates were similar between groups, except that the DCB group had higher rates of post-procedure mild hematuria and dysuria (11.4% versus 2.1% for both event types). A limitation of this study is that Optilume DCB was compared to dilation and DVIU, so it is unknown how this treatment compares to urethroplasty, which is considered standard of care for urethral stricture. The authors also acknowledged that these early positive results could be impacted by surgeons dilating the urethra with Optilume, but in this study the immediate post-treatment diameter was similar between treatment groups.

Single-Arm Studies

DeLong (2022) published interim, one-year results from the ROBUST II study that investigated the safety and efficacy of a paclitaxel-coated balloon for treatment of recurrent urethral strictures. The study included 16 adult males with a single anterior urethral stricture less than or equal to three cm in length, and who had at least two prior stricture treatments.[33] The primary safety endpoint was the rate of treatment-related serious complications 90 days after treatment. Efficacy outcomes were symptomatic assessments (IPSS), erectile function (IIEF), Qmax, and anatomic success defined by the ability to pass a 16F flexible cystoscope through the treatment site. Anatomic success was achieved for 73% of participants at six months. Average IPSS improved from 18.4 to 6.0 at one year ($p<0.001$). Qmax improved from 6.9 mL/s to 20.8 mL/s ($p<0.001$). There was no change in IIEF. Four participants received additional

treatment for urethral stricture within one year. No treatment-related serious complications occurred. This study is limited by small sample size and lack of a comparison group.

Virasoro (2020) published interim, one-year results from the ROBUST I study that enrolled 53 males with bulbar urethral strictures less than or equal to two cm with one to four prior endoscopic treatments.[34] All participants were treated with mechanical balloon dilation or DVIU prior to drug-coated balloon treatment. 46 participants completed the 12 month follow up. The preliminary efficacy endpoint was anatomic success, defined by urethral lumen greater than or equal to 14Fr at 12 months. The primary safety endpoint was serious complications through 90 days. Anatomic success was achieved in 32 of 46 participants (70%; 95% CI 54 to 82%) at 12 months. The 14 failures included seven cystoscopic recurrences, five retreatments, and two patients who exited the study early due to symptom recurrence. There were no serious adverse events related to the treatment within 90 days and no serious adverse events related to the procedure at 12 months. Follow-up is planned through five years post-treatment for the ROBUST I study, and published two- and three-year outcomes are discussed below.

Mann (2021) published two-year outcomes of the ROBUST I study in which 46 participants completed the 24-month follow-up.[35] The primary efficacy endpoint was greater than or equal to 50% improvement in IPSS at 24 months, and the primary safety endpoint was serious urinary adverse events. 43% of participants had undergone at least one or more previous urethral dilation procedure. The primary endpoint was achieved in 32 of 46 participants (70%), and baseline IPSS improved from a mean of 25.2 to 6.9 at 24 months ($p<0.0001$). There were no treatment-related serious adverse events at 24 months. There were 71 mild-to-moderate adverse events, most frequently: urinary tract infection (17%), fever (8%), dysuria (7%), acute urinary retention (6%), and headache (6%).

Virasoro (2022) published three-year outcomes of ROBUST I which included results for 33 participants who completed the three-year follow-up visit and 10 patients who experienced clinical failures at previous visits (n=43).[36] The primary efficacy endpoint, greater than or equal to 50% reduction in IPSS, occurred in 29 of 43 participants (67%). Average IPSS improved from 25.2 at baseline to 5.5 at three years ($p<0.0001$). 33 of 43 participants (77%) did not require retreatment. Significant improvements were also observed in quality of life, urinary flow rate, and post-void residual urine volume. Similar to previous results at earlier follow-ups, device-related adverse events were mild or moderate and resolved quickly after onset. There were no serious treatment-related adverse events. The ROBUST I study is limited by lack of a comparator group and small sample size.

Section Summary: Optilume® Drug Coated Urethral Dilation Catheter

Data from one RCT and two single-arm studies reported that the Optilume® Urethral Drug Coated Balloon significantly reduced stricture recurrence, increased urinary flow rate, and improved urinary symptom scores. The RCT reported significantly greater improvement with the drug-coated balloon than with endoscopic management. Drug-coated balloon treatment was more durable than endoscopic treatment at one year follow-up. Limitations of the RCT are that most participants had bulbar urethral strictures, so it is unknown whether the treatment is generalizable to all types of urethral strictures; hematuria was more common with the drug-coated balloon; and this treatment has not been compared to urethroplasty which is most successful for treating recurrent strictures. In these studies, long-term follow-up beyond one-year occurred only in small single-arm studies. Further, additional long-term data on paclitaxel

in tissues is needed to assess device safety. There is not yet enough evidence that the technology results in an improvement in the net health outcome.

PROSTATIC URETHRAL SCAFFOLD DEVICE

Clinical Context and Therapy Purpose

A prostatic urethral scaffold or "spring" nitinol device (e.g., Zenflow Spring®) is used to treat urinary obstruction and improve urinary flow in people with BPH. The spring device maintains the patency of the urethra within the prostate. The device is placed using minimally invasive surgery and is designed to be permanent.

Non-randomized Studies

The available evidence for the Zenflow Spring® is limited to safety and feasibility studies with few subjects that were funded by Zenflow. Gilling (2024) compiled data from three pilot studies of the Zenflow Spring® involving 72 participants.[37] The studies found significant symptom improvement from baseline with up to 24 months follow-up. However, one study of 35 subjects found that 6/35 subjects had serious adverse events, primarily attributed to the surgeons' learning curve. At one year, 6/35 subjects required explantation. Three explantations were due to urinary retention, two were due to lack of effectiveness, and one explantation was required due to an unrelated ureter cancer.

Section Summary: Prostatic Urethral Scaffold Device

Evidence for prostatic urethral scaffold devices (e.g., Zenflow Spring®) is limited to small non-randomized studies focused on safety and feasibility that do not compare prostatic urethral scaffold devices to other treatments for BPH. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

PRACTICE GUIDELINE SUMMARY

AMERICAN UROLOGICAL ASSOCIATION

In 2023, the American Urological Association (AUA) published updated guidelines on the management of lower urinary tract symptoms attributed to benign prostatic hyperplasia.[38] The guidelines include temporary implanted prostatic devices (TIPD) on the list of surgical therapies for BPH, with an evidence level designation "expert opinion." The guideline states, "TPID may be offered as a treatment option for patients with LUTS/BPH provided prostate volume is between 25 and 75g and lack of obstructive median lobe. The guideline does not address the use of drug-coated balloon catheters to treat LUTS/BPH.

In 2023, the AUA published an amendment to the 2016 guidelines for the treatment of urethral stricture disease.[12] These guidelines state, "Surgeons may offer urethral dilation or direct visual internal urethrotomy, combined with drug-coated balloons, for recurrent bulbar urethral strictures less than three cm in length (Conditional Recommendation; Evidence Level: Grade B)."

SUMMARY

TEMPORARY IMPLANTED NITINOL DEVICES

There is not enough research to show that temporarily implanted nitinol devices (e.g., iTind) work better than established treatments to improve health outcomes for people with benign prostatic hyperplasia. No clinical guidelines based on research recommend temporarily implanted nitinol devices to treat benign prostatic hyperplasia. Therefore, temporarily placed nitinol devices (e.g., iTind) are considered investigational for all indications, including but not limited to treatment of symptoms due to benign prostatic hyperplasia.

OPTILUME® BENIGN PROSTATIC HYPERPLASIA CATHETER SYSTEM

There is not enough research to show that drug-coated balloon catheters (e.g., Optilume® BPH) work better than established treatments to improve health outcomes for people with benign prostatic hyperplasia. No clinical guidelines based on research recommend drug-coated balloon catheter systems to treat benign prostatic hyperplasia. Therefore, drug-coated balloon catheter systems (e.g., Optilume® BPH) are considered investigational for all indications, including but not limited to treatment of symptoms due to benign prostatic hyperplasia.

OPTILUME® URETHRAL DRUG COATED BALLOON

There is not enough research to show that drug-coated balloon catheters (e.g., Optilume® Urethral Drug Coated Balloon) work better than established treatments to improve health outcomes for people with urethral stricture or stenosis. The AUA recommends drug-coated balloons conditionally and only in combination with established endoscopic management of urethral strictures. Therefore, drug-coated balloon catheter systems (e.g., Optilume® Urethral Drug Coated Balloon) are considered investigational for all indications, including but not limited to treatment of symptoms due to urethral stricture or stenosis.

PROSTATIC URETHRAL SCAFFOLD DEVICE

There is not enough research to show that prostatic urethral scaffold devices (e.g., Zenflow Spring®) work better than established treatments to improve health outcomes for people with urinary obstruction from benign prostatic hyperplasia. No clinical guidelines based on research recommend prostatic urethral scaffold devices to treat benign prostatic hyperplasia. Therefore, use of prostatic urethral scaffold devices (e.g., Zenflow Spring®) is considered investigational for all indications, including but not limited to treatment of symptoms due to benign prostatic hyperplasia.

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CODES

Codes	Number	Description
CPT	0619T	Cystourethroscopy with transurethral anterior prostate commissurotomy and drug delivery, including transrectal ultrasound and fluoroscopy, when performed
	0941T	Cystourethroscopy, flexible; with insertion and expansion of prostatic urethral scaffold using integrated cystoscopic visualization
	0942T	Cystourethroscopy, flexible; with removal and replacement of prostatic urethral scaffold
	0943T	Cystourethroscopy, flexible; with removal of prostatic urethral scaffold
	52284	Cystourethroscopy, with mechanical urethral dilation and urethral therapeutic drug delivery by drug-coated balloon catheter for urethral stricture or stenosis, male, including fluoroscopy, when performed
	53855	Insertion of a temporary urethral stent, including urethral measurement
	53865	Insertion of temporary device with cystourethroscopy for ischemic remodeling of bladder neck and prostate
	53866	Catheterization with removal of temporary device for ischemic remodeling of bladder neck and prostate
HCPCS	~~C9769~~ None	~~Cystourethroscopy, with insertion of temporary prostatic implant/stent with fixation/anchor and incisional struts (Nitinol, iTind device)~~ (Deleted 01/01/2025)

Date of Origin: *March 2023*