07.01.101 Urethral Drug-Coated Balloons for the Treatment of Urethral Stricture(s)

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Related Policies:

- 07.01.95 Transurethral Water Vapor Thermal Therapy (Rezum) and Transurethral Waterjet Ablation (Aquablation) for Benign Prostatic Hypertrophy
- 07.01.97 Miscellaneous Minimally- Invasive Treatments for Benign Prostatic Hyperplasia

Summary

Description

Urethral drug-coated balloons (e.g., Optilume®) are devices that use balloon catheters to open the urethra or prostate and transfer paclitaxel from the balloon to help with obstructive urinary symptoms. The drug-coated balloon catheters have been proposed as minimally invasive alternatives to endoscopic management, transurethral resection of the prostate, and urethroplasty to treat symptoms associated with an obstructive urinary tract for urethral stricture.

Summary of Evidence

For individuals who utilize a urethral drug-coated balloon for the treatment of obstructive urinary symptoms associated with urethral stricture(s), the evidence includes systematic reviews, a randomized controlled trial (RCT) and several prospective and retrospective single arm studies. Relevant outcomes are symptoms, change in disease status, and treatment-related morbidity. A systematic review of Optilume Drug-Coated Balloon for urethral strictures found a pooled recurrence-free rate of 80.83%, with a complication rate of 9.5%, but short follow-up periods and the paucity of RCTs limited interpretation of these findings. The RCT (Elliott, 2022) reported significantly reduced stricture recurrence, increased urinary flow rate, and improved urinary symptom scores for those who were treated with the urethral drug-coated balloon versus endoscopic management. Additionally, there was significantly greater improvement with the treatment of a urethral drug-coated balloon versus endoscopic management. At the 1-year follow-up the treatment with the urethral drug-coated balloon was more durable than the treatment with endoscopic management. Limitations included most individuals had bulbar urethral strictures, thus not known if the treatment is generalizable to all types of urethral strictures. Additionally, hematuria was more prevalent in the treatment group who utilized the urethral drug-coated balloon. Lastly, urethral drug-coated balloon has not been compared to urethroplasty which is most advantageous for recurrent stricture treatment. Long-term follow-up beyond 2-years only occurred in small single-arm studies. Additional randomized comparative evidence is needed to permit conclusions about the effectiveness of treatment with urethral drug-coated balloon compared with urethroplasty. The evidence is insufficient to determine the technology results in an improvement in the net health outcomes.

Additional Information

None

OBJECTIVE

The objective of this evidence review is to determine whether the use of a drug-coated balloon improves the net health outcomes in individuals with obstructive urinary symptoms associated with urethral stricture(s).

PRIOR APPROVAL

Not applicable.

POLICY

The use of a urethral drug-coated balloon for the treatment of obstructive urinary symptoms associated with urethral stricture(s) (i.e. Optilume®) is considered **investigational** because the evidence is insufficient to determine the technology results in an improvement in the net health outcomes.

POLICY GUIDELINES

The International Prostate Symptom Score (IPSS)

The International Prostate Symptom Score (IPSS) can be utilized to measure the severity of lower urinary tract symptoms. It is a validated, reproducible scoring system to assess disease severity and response to therapy. The IPSS is made up of 7 questions related to voiding symptoms. A score of 0 to 7 indicates mild symptoms, 8 to 19 indicates moderate symptoms and 20 to 35 indicates severe symptoms. It is not a reliable diagnostic tool for lower urinary tract symptoms (LUTS) suggestive of BPH but can be used to quantitatively measure LUTS after a diagnosis is made.

Calculator: International Prostatism Symptom Score (IPSS)

"Over the past month, how often have you had a sensation of not emptying your bladder completely after you finished urinating?

- Not at all (0 points)
- Less than 1 time in 5 (1 point)
- Less than half the time (2 points)
- About half the time (3 points)
- More than half the time (4 points)
- Almost always (5 points)

Over the past month, how often have you had to urinate again less than 2 hours after you finished urinating?

- Not at all (0 points)
- Less than 1 time in 5 (1 point)
- Less than half the time (2 points)
- About half the time (3 points)
- More than half the time (4 points)
- Almost always (5 points)

Over the past month, how often have you found you stopped and started again several times when you urinated?

- Not at all (0 points)
- Less than 1 time in 5 (1 point)
- Less than half the time (2 points)
- About half the time (3 points)
- More than half the time (4 points)
- Almost always (5 points)

Over the past month, how often have you found it difficult to postpone urination?

- Not at all (0 points)
- Less than 1 time in 5 (1 point)
- Less than half the time (2 points)
- About half the time (3 points)
- More than half the time (4 points)
- Almost always (5 points)

Over the past month, how often have you had a weak urinary stream?

- Not at all (0 points)
- Less than 1 time in 5 (1 point)
- Less than half the time (2 points)
- About half the time (3 points)
- More than half the time (4 points)
- Almost always (5 points)

Over the past month, how often have you had to push or strain to begin urination?

Not at all (0 points)

- Less than 1 time in 5 (1 point)
- Less than half the time (2 points)

- About half the time (3 points)
- More than half the time (4 points)
- Almost always (5 points)

Over the past month, how many times did you most typically get up to urinate from the time you went to bed at night until the time you got up in the morning?

- Not at all (0 points)
- Less than 1 time in 5 (1 point)
- Less than half the time (2 points)
- About half the time (3 points)
- More than half the time (4 points)
- Almost always (5 points)"

Coding

See the Codes table for details.

BACKGROUND

Urethral Stricture

The urethral lumen can have a stricture after chronic fibrosis and narrowing. A urethral stricture can be caused by interventions such as surgery, utilization of urethral instrumentation, cancer treatment, acute injury, and inflammatory conditions. When narrowing occurs in the anterior urethra is called a urethral stricture. When the narrowing occurs in the posterior urethra it is called stenosis. Individuals who have a stricture often report non-specific symptoms such as a reduced urinary stream, incomplete bladder emptying, post-void residual increase, reduced ejaculation force, urinary spraying urine stream, or painful urination. These symptoms often overlap with other conditions such as an upper or lower urinary tract infection. According to the American Urological Association (AUA), "in high income countries, the most common etiology of urethral stricture is idiopathic (41%) followed by iatrogenic (35%). Late failure of hypospadias surgery and stricture resultant from endoscopic manipulation (e.g., transurethral resection) are common iatrogenic reasons. In comparison, trauma (36%) is the most common cause in low- and middle-income countries, reflecting higher rates of road traffic injuries, less developed trauma systems, inadequate roadway systems, and conceivably socioeconomic factors leading to a higher prevalence of trauma-related strictures."

Diagnosis

In order to diagnose a urethral stricture, the provider will start by reviewing the individual's history, physical examination, and urinalysis. If a urethral stricture is suspected providers typically use a combination of measures including patient reported symptoms, ultrasound post-void residual assessment and uroflowmetry. For a provider to make the diagnosis of a urethral stricture a urethra-cystoscopy, voiding cystourethrography, ultrasound urethrography, and retrograde urethrography are commonly used.

Management

The urgency to fix a urethral stricture (urgent vs. non-urgent) is determined on the length and location of the stricture. For the initial non urgent treatment of bulbar urethral strictures that are considered short (< 2 centimeters [cm]), urethral dilation, direct visual internal urethrotomy (DVIU), or urethroplasty are commonly used. However, high rates of stricture recurrence have been reported.

In an attempt to address these high stricture recurrence rates, several types of adjunctive treatments have been explored. These include brachytherapy, captopril, drug-coated (paclitaxel) balloon dilatation,

drug-coated (e.g., steroids) catheters, hyaluronidase, intralesional injection with steroids, mitomycin C, oral steroids, platelet-rich plasma. One such newer adjunctive treatment options is the Optilume® Urethral Drug Coated Balloon.

According to the FDA's summary of safety and effectiveness data, "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. Optilume® 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." "The Optilume® Urethral Drug Coated Balloon is contraindicated for use in patients with known hypersensitivity to paclitaxel or structurally related compounds and in patients with urologic implants such as penile implants or artificial urinary sphincters."

Regulatory Status

In December 2021, the Optilume® Urethral Drug Coated Balloon (Urotronic, Inc.) received premarket approval from the U.S. FDA (P210020, product code: QRH.) "The Optilume® Urethral Drug Coated Balloon is indicated for the treatment of obstructive urinary symptoms associated with anterior urethral stricture in adult" XY individuals "for urethral stricture $\geq$ 3 cm in length."

RATIONALE

This evidence review was created in March 2024 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through March 2026.

Evidence reviews assess the clinical evidence to determine whether the use of 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 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 technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 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 (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs 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.

Urethral Drug-Coated Balloon for Obstructive Urinary Symptoms Associated with Anterior Urethral Stricture

Clinical Context and Therapy Purpose

Use of a drug-coated urethral balloon in XY individuals 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, endoscopic management or urethroplasty.

Populations
The relevant population of interest is individuals with obstructive urinary symptoms associated with anterior urethral stricture.

Interventions
The intervention being considered is a urethral drug-coated balloon (e.g., Optilume®).

Comparators
Urethral dilation with an uncoated balloon, endoscopic management or urethroplasty.

Outcomes
Relevant outcomes include patient reported measures such as the IPSS to assess symptoms, uroflowmetry to determine severity of obstruction, and evaluation of stricture diameter with urethroscopy, retrograde urethrography, or ultrasound urethrography, as well as change in disease status, and treatment-related morbidity.

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.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Review
Estaphanous et. al. (2024) conducted a systematic review and meta-analysis of evidence on the efficacy and safety of Optilume.[1] Reviewers searched 4 databases in November 2024 (PubMed, Scopus, Google Scholar, and the Cochrane Library). Seven studies were included (N= 457), comprised of the ROBUST III RCT, three prospective cohort studies (including ROBUST I and II), and three retrospective cohort studies. Analyses found a recurrence-free rate of approximately 80.83% for Optilume, with a complication rate of 9.5%. Review authors reported evidence limitations included short follow-up periods and the limited number of RCT's.

Li et. al. (2024) also conducted a systematic review and meta-analysis on the efficacy and safety of balloon dilation more generally for the treatment of male urethral strictures. However, as the search strategy for this systematic review only extended through July 2022 and only included two of the seven studies specific to the Optilume drug-coated balloon that were included by Estaphanous et. al. (2024), a detailed analysis of its findings will not be provided herein.

Randomized Controlled Trial
Elliot et al. (2022) reviewed the ROBUST III multi-center, single-blind trial for one-year outcomes evaluating the safety and efficacy of the Optilume® drug-coated balloon (DCB) for recurrent anterior

urethral strictures treatment. “Eligible patients were adult males with anterior strictures ≤12 Fr. in diameter and ≤ 3 cm in length, at least 2 prior endoscopic treatments, International Prostate Symptom Score ≥ 11 and maximum flow rate <15 ml per second. A total of 127 subjects were enrolled at 22 sites. The primary study end point was anatomical success (≥ 14 Fr by cystoscopy or calibration) at 6 months. Key secondary end points included freedom from repeat treatment, International Prostatic Symptom Score and peak flow rate. The primary safety end point included freedom from serious device- or procedure-related complications.” “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.” The standard of care at each site was endoscopic control treatments and included treatment serial dilation with urethral sounds, dilation with an (uncoated) balloon, DVIU, or any combination of these treatments. Follow up post-procedure started when the foley catheter was removed (days 2-5 in both groups), “30 days, three months, six months, and 1 year”. The anatomical success at six months was “74.6% in the DCB group and 26.8% in the control group”. This resulted with a difference estimated at 44.4% ($p<0.0001$). At 1 year the freedom from repeat intervention was “significantly higher for the DCB group than the control group (83.2% versus 21.7%, $p<0.0001$).” “Both groups showed a significant increase in Qmax from baseline to 30 days, with control participants exhibiting a marked deterioration beginning at the 3-month visit. By 1 year, the average Qmax in the DCB group was nearly double that of the control group. The post-void residual (PVR) urine volume in the control group was higher than baseline at 6 months and 1 year.” Adverse events were similar between groups, “except that the DCB group had higher rates of post-procedure mild hematuria and dysuria (11.4% vs 2.1%)”. A study limitation is it’s unknown how the Optilume DCB compares to urethroplasty because the study only compared the Optilume DCB to urethral dilation and DVIU, as they are considered the standard of care for urethra stricture. Additionally, surgeons were not blinded. “It is possible that the better results seen with DCB were due to dilation to a larger lumen size than in controls; however, post-treatment urethrogram estimated the lumen diameters were not different between groups, and a subset analysis of just patients treated with 30 Fr. balloons showed similar findings to the overall analysis.”

VanDyke et al (2023) reviewed the 2-year findings from the DCB group in the ROBUST III RCT. At 2-years the advantage from the freedom from repeat intervention remained stable “significantly higher for the DCB group than the control group (77.8% vs 23.6%).” The results were further limited by the occurrence of an increase in participant drop-outs at 2-years compared to 1-year. This limits conclusions about whether the DCB improves the net health outcome.

Additionally, Srikanth et al (2025) reported the 3-year safety and efficacy outcomes from the Optilume® DCB group (n=45 of 79) of the ROBUST III trial. At 3-year follow-up, 48% of patients that underwent DCB achieved ≥30% IPSS improvement without repeat intervention. Improvements in the Qmax and post-void residual volumes were sustained relative to baseline, although gradual decline over time was observed, consistent with the natural history of recurrent stricture disease. Adverse events such as hematuria, dysuria, or urinary tract infection were generally transient and mild. No late treatment-related serious adverse events have been reported. High-risk individuals with multiple prior endoscopic dilations or longer stricture lengths, demonstrated similar treatment responses, suggesting consistent efficacy across clinically challenging populations. As an extension of the ROBUST III study, the limitations are consistent with that of the initial phase as summarized above. Additionally, as with the 2-year study, the 3-year results are further limited by the occurrence of additional participant drop-outs due to various reasons including failure of treatment and adverse events.

Single-Arm Studies

Additionally, multiple small single-arm prospective and retrospective studies have investigated the safety and efficacy of the Optilume® DCB. The largest of the prospective studies include the ROBUST I and II

studies. DeLong (2022) published interim, one-year results from the ROBUST II study in 16 adult males. For the prior ROBUST I study, which originally enrolled 53 males with bulbar urethral strictures less than or equal to two cm with one to four prior endoscopic treatments, results have been published at 1-year (Virasoro 2020), two-years (Mann 2021, n=46), three-years (Virasoro 2022, n=33)) and 5 years (DeLong 2025, n=31). Although these studies provide longer-term follow-up than the ROBUST III RCT, no definitive conclusions about the net health outcome can be made based on their findings due to their lack of a comparator group and small sample sizes.

Among the larger retrospective single-arm studies, notable is a multi-institutional review by VanDyke et. al. (2025) of 122 male individuals with *recurrent* strictures following urethroplasty; which was a condition excluded in the pivotal ROBUST III RCT. In individuals with a median of 3.5 and 2.9 months of follow-up, respectively, they found similarly high early success rates (i.e., freedom from re-intervention, 80.0% vs 88.9%, p=0.338) after treatment with DCB for those with and without a history of urethroplasty.

Section Summary: Urethral Drug-Coated Balloon for Obstructive Urinary Symptoms Associated with Anterior Urethral Stricture

The urethral DCB (i.e. Optilume®) significantly reduced stricture recurrence, increased urinary flow rate, and improved urinary symptom scores compared to endoscopic management according to one RCT by Elliott (2022). At the 1-year follow-up, the treatment with the urethral DCB (i.e. Optilume®) was more durable than the treatment with endoscopic management. The durability advantage persisted at 3-years, however interpretation of this finding is limited by further participant drop-outs. There were RCT limitations including most individuals had bulbar urethral strictures, thus not known if the treatment is generalizable to all types of urethral strictures. Additionally, hematuria was more prevalent in the treatment group who utilized the urethral DCB (i.e. Optilume®). Lastly, the urethral DCB (i.e. Optilume®) has not been compared to urethroplasty which is most advantageous for recurrent stricture treatment. Long-term follow-up beyond 2 -year only occurred in small single-arm studies. The evidence is insufficient to determine the technology results in an improvement in the net health outcomes.

SUPPLEMENTAL INFORMATION

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

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Urological Association (AUA)

In 2023, the AUA published an amendment to the 2016 guidelines for the treatment of urethral stricture disease. 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).”

European Association of Urology (EAU)

In 2023 the EAU published a guideline on Urethral Strictures which stated:

- “Drug (paclitaxel)-coated balloon dilatation is associated with higher anatomic patency rates (at six months) and lower risk of retreatment (at one year) as compared to standard dilatation/DVIU in patients with short (< 3 cm), bulbar strictures that underwent at least two prior failed endoscopic treatments. (LE: 1b).”

- "Offer drug (paclitaxel)-coated balloon dilatation for a short (< 3 cm) bulbar stricture recurring after at least two prior endoscopic treatments, but only in patients for whom urethroplasty is not an option. (Strength rating: weak)".

- "Paclitaxel was detected in semen up to six months after treatment which urges for contraception if the partner has child-bearing potential".

National Institute for Health and Care Excellence (NICE)

In 2022 NICE published a guideline on Optilume for treating recurrent bulbar urethral strictures which stated,” Optilume done in an outpatient setting could reduce the waiting times for treatment of recurrent bulbar urethral strictures. The comparative clinical evidence shows that Optilume is effective in the short term (up to 2 years). But how effective and safe it is in the long term (up to 5 years) compared with standard endoscopic management is uncertain. So, more long-term data collection is needed on retreatment rates and patient-reported outcomes.”

Ongoing and Unpublished Clinical Trials

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

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CODES

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

Codes	Number	Description
CPT		
	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
HCPCS		

Codes	Number	Description
	No code(s)	
Type of Service	Surgery	
Place of Service	Outpatient	

POLICY HISTORY

Date	Reason	Action
March 2026	Annual Review	Policy Renewed
March 2025	Annual Review	Policy Renewed
March 2024		New Medical Policy Created

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

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