
Medical Policy



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***Current Policy Effective Date: 7/1/25**
(See policy history boxes for previous effective dates)

Title: Drug Coated Balloon for Urethral Strictures (i.e., Optilume Urethral Drug Coated Balloon)

Description/Background

Urethral stricture is chronic fibrosis and narrowing of the urethral lumen caused by acute injury, inflammatory conditions, and iatrogenic interventions including urethral instrumentation, surgery, and prostate cancer treatment. This condition may lead to weak or slow urine stream, frequent urination, pain or burning during urination, urinary tract infection, acute urinary retention, and/or can lead to permanent bladder or kidney damage.

Drug-coated balloon catheter system(s), in conjunction with urethral dilation or direct visual internal urethrotomy, has been proposed as a minimally invasive alternative to urethroplasty (gold standard) to treat urinary tract symptoms associated with recurrent urethral strictures. The device utilizes a balloon catheter to dilate the anterior urethra and deliver paclitaxel, an antimitotic agent that inhibits cell proliferation, to reduce the recurrence of strictures.

The incidence of urethral stricture in males is estimated to be between 200-1200 cases per 100,000 individuals. There is a significant increase in occurrence seen in men over the age of 55, making it more prevalent in older populations. The majority of these strictures occur in the anterior urethra, particularly the bulbar urethra.

The American Urological Association (AUA; 2023) recommends that once a urethral stricture is diagnosed, clinicians should determine the length and location of the stricture in order to inform treatment. After a period of urethral rest, patients with short (<2 cm) bulbar urethral stricture may be treated endoscopically with urethral dilation or direct visual internal urethrotomy. Urethroplasty may be performed by an experienced surgeon in participants with first time or recurrent anterior and posterior urethral strictures. The best treatment option for urethral stricture in female subjects is urethroplasty using oral mucosa grafts or vaginal flaps rather than endoscopic treatment.

Regulatory Status

In 2021, the Optilume® Urethral Drug Coated Balloon (Urotronic Inc.) PMA was approved by the U.S. Food and Drug Administration (FDA) (P210020). This device is intended for the treatment of patients with obstructive urinary symptoms associated with anterior urethral stricture. It is designed to be used in adult males for urethral strictures of ≤3 cm in length. Product code: QRH

In Oct 2023, Laborie Medical Technologies acquired Urotronic Inc.

Medical Policy Statement

The use of a drug-coated balloon catheter system (i.e., Optilume® Urethral Drug Coated Balloon) is considered established. The evidence is sufficient to determine that the technology results in an improvement in net health outcomes.

Inclusionary and Exclusionary Guidelines

Inclusions:

Urethral drug coated balloons (i.e., Optilume® Urethral Drug Coated Balloon) when **ALL** of the following are met:

- Recurrent bulbar urethral stricture
- At least 2 previous endoscopic procedures have failed
- Stricture is ≤ 3 cm in length

Exclusions:

- Initial treatment of a bulbar stricture
- Treatment of strictures other than a bulbar stricture
- Repeat use of a urethral drug coated balloon to treat a stricture
- When the above inclusionary criteria are not met

Note: Per FDA Summary of Safety and Effectiveness Data information, men with partners of child-bearing potential should use highly effective contraceptive and avoid fathering children until at least 6 months after treatment with the Optilume Drug Coated Balloon. The risks associated with paclitaxel concentrations in semen are unknown.

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:

52284

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

N/A

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

Urethroplasty is considered the gold standard for the treatment of urethral stricture with an 80-90% success rate. However, the most commonly performed procedures are urethral dilation and/or direct vision internal urethrotomy (DVIU). Dilation/DVIU is successful in <50%, especially in recurrent disease. Optilume aimed to fill the gap by being less invasive than urethroplasty but more successful than urethral dilation or DVIU for urethral strictures.

The goal of the ROBUST I trial was to assess the safety and efficacy of the Optilume® drug coated balloon (DCB) in men with recurrent urethral strictures. Virasoro et al (2022) discussed the 3 year findings of the ROBUST I trial. Adult men with recurrent bulbar urethral strictures ≤ 2 cm in length and 1–4 prior endoscopic interventions were treated with the Optilume DCB. Functional success was defined as $\geq 50\%$ reduction in International Prostate Symptom Score (IPSS) without need for retreatment. Other outcomes included quality of life, maximum flow rate, post-void residual urine volume, erectile function, and freedom from repeat intervention. Of the 55 enrolled and treated men, thirty-three men completed the 3-year visit, with 10 participants experiencing clinical failures at previous visits, giving a total of 43 subjects evaluable for the functional success endpoint. Functional success was achieved in 67% (29/43) and freedom from retreatment in 77% (33/43). Average IPSS improved from 25.2 at baseline to 5.5 at 3 years ($p < 0.0001$). Significant improvements were observed in quality of life, flow rate, and post-void residual urine volume. Erectile function was not affected by treatment. Device-related adverse events were mild or moderate in nature and resolved quickly after onset. Symptomatic improvement after treatment with the Optilume DCB was maintained through 3 years in a population highly susceptible to recurrent urethral stricture disease. Authors concluded that this minimally invasive therapy is safe with no negative impact on sexual function.

The ROBUST III study is a randomized controlled trial comparing the Optilume® Drug Coated Balloon (DCB) against direct visual internal urethrotomy (DVIU) or dilation. Eligible participants 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. One-hundred and twenty-seven men were enrolled at 22 sites. Participants were randomized 2:1 to receive treatment with the Optilume drug coated balloon versus endoscopic management (standard of care). Forty-eight were randomised to standard of care dilation and 79 to the drug coated balloon therapy. Long-term endpoints included freedom from repeat treatment, International Prostate Symptom Score (IPSS), and peak urinary flow rate (Qmax). Freedom from repeat intervention was determined via Kaplan–Meier analysis and used a log-rank test for comparison of the rate in the Optilume group through 2 years to the rate in the Control group through 1 year. Limitations of the study included the surgeons not being blinded to the type of treatment administered, subjects were unblinded after 6 months which could impact how they completed the questionnaires and their interest in

retreatment for recurrent symptoms. A lack of standardization existed as surgeons were allowed to choose the method of pre-dilation, the majority of strictures in the control arm were dilated to 24Fr whereas those in the treatment arm were dilated to 30Fr.

Elliott et al (2022) released 6 month and 1 year outcomes of the ROBUST III study. At 6 months, the rate of anatomic success (defined by the ability to pass a flexible ≥ 14 Fr cystoscope) was 75% for Optilume and 27% for dilation/DVIU. Several different 1-year outcomes were also superior for Optilume vs dilation/DVIU: freedom from repeat intervention was 83% vs 22%, urinary symptoms as measured by the International Prostate Symptom Score were 9 vs 20 and maximum urinary flow rate was 16 vs 8 ml per second, respectively. Most side effects were similar across treatments except hematuria and dysuria, which were more common after Optilume (11% vs 2% for both events). Authors concluded that Optilume is safe and superior to standard direct vision internal urethrotomy/dilation for the treatment of recurrent anterior urethral strictures <3 cm in length.

VanDyke et al (2024) published a 2 year result of the intervention arm of the ROBUST III randomized trial. Freedom from repeat intervention was higher in the Optilume drug coated balloon arm at 2 years versus the control arm at 1 year (77.8% vs. 23.6%, $p < 0.001$). The average IPSS improved from 22.0 at baseline to 9.0 at 1 year and 10.1 at 2 years ($p < 0.001$) in the Optilume group. During the follow-up period, there were 15 treatment failures and 2 non-study-related deaths. Treatment-related adverse events were rare and generally self-limiting (hematuria, dysuria and urinary tract infection). Authors concluded that Optilume delivers improvements in both objective and subjective voiding parameters that are maintained over a 2-year follow-up period. Optilume appears to offer a safe and superior alternative to standard endoscopic management for treating short recurrent anterior urethral strictures and is a viable treatment alternative for those men who wish to avoid or delay formal urethroplasty.

DeLong et al (2024) announced 4 year interim results on the ROBUST III trial at the 93rd annual meeting of the American Urological Association. Subjects randomized to receive the DCB had an average of 3.2 prior treatments and an average stricture length of 1.6 cm (46% ≥ 2 cm), with 8/79 (10.1%) having penile strictures and 9/79 (11.4%) having received prior pelvic radiation. IPSS significantly improved from 21.9 at baseline to 12.6 at 4 years, which showed slight deterioration from the 3 year (11.3), 2 year (10.1) and 1 year (9.0) results. Qmax significantly improved from a baseline of 7.7 mL/sec to 13.2 mL/sec at 4 years, which is in line with the 3 year (12.0) and 2 year (13.9) data. Freedom from repeat intervention for DCB subjects was estimated to be 71%. No late-onset treatment related adverse events were observed. Authors concluded that the Optilume® DCB continues to achieve significant improvements in symptoms, flow, and reintervention rates through 4 years post treatment.

Wessells et al (2023) reported on the American Urological Associations (AUA) guidelines for urethral stricture disease. It was determined that urethral strictures which were previously treated with dilation/DVIU had an 80% failure rate when treated with another endoscopic procedure. Concerns were voiced regarding repeated endoscopic treatments potential to cause longer strictures and increase the complexity of subsequent urethroplasty. Based on outcomes from both the ROBUST I and ROBUST III trials, The AUA released a recommendation for the possible use of DCB in recurrent bulbar urethral strictures. Since the trials were not powered to assess results in subjects with penile urethra strictures the Panel recommends that drug-coated balloons are restricted to treat subjects with recurrent bulbar urethral strictures.

Estaphanous et al (2024) analyzed 7 studies and 457 participants in a meta-analysis to determine the safety and efficacy of DCB therapy for anterior urethral strictures. The selected studies comprised one randomized controlled trial (RCT), 3 prospective cohort studies, and 3 retrospective cohort studies. Follow-up duration ranged from 3 months to 5 years, with most strictures located in the anterior bulbar urethra and measuring under 3 cm in length. The primary outcome assessed across the studies was the success rate, as demonstrated by improvement in the IPSS and QMax. The secondary outcomes included recurrence and complication rates. The results consistently showed significant improvement in IPSS and QMax postoperatively. Recurrence and complication rates were generally low, with a high rate of freedom from re-intervention, indicating that the procedure is both safe and effective for managing urethral strictures. While the results are promising, this review also highlights some limitations. Some studies had relatively short follow-up periods, often limited to 1 or 2 years, potentially missing longer-term recurrence outcomes. Additionally, the limited number of randomized control trials (RCTs) restricts comparative data with other treatments, such as urethroplasty. Authors concluded that although this systematic review and meta-analysis provide strong evidence that Optilume is a valuable addition to urethral stricture treatment, particularly for subjects with shorter, anterior strictures, larger RCTs with extended follow-up are needed to further confirm Optilume's long-term outcomes.

For individuals who have anterior urinary strictures and receive treatment via an Optilume drug-coated balloon the evidence includes small trials, some guideline support, and a meta-analysis. Key outcomes included significant reductions in symptom scores, as measured by the International Prostate Symptom Score (IPSS), and improvements in urinary flow rates (QMax). The recurrence-free rate was approximately 83% at the 6 month and 1 year outcome marks. At 2 years 77.8% of participants did not have or need repeat interventions. The 4 year interim results indicated that the Qmax had significantly improved from a baseline of 7.7 mL/sec to 13.2 ml/sec and that freedom from repeat interventions for DCB participants was estimated to be 71%. The complication rate, calculated as a weighted average across studies, was low at 9.5%, with most adverse events being mild and temporary, including dysuria and urinary tract infections. The meta-analysis determined that recurrence and complication rates were generally low, with a high rate of freedom from re-intervention, indicating that the procedure is both safe and effective for managing urethral strictures. All factors which suggest that Optilume may offer an acceptable alternative to endoscopic dilation/DVIU. The evidence is sufficient to determine that the technology results in an improvement in the net health outcomes of a specified population.

Supplemental Information

American Urological Association

In 2023, the American Urological Association (AUA) published guidelines on the surgical evaluation and treatment of lower urinary tract symptoms (LUTS) attributed to urethral stricture disease. These guidelines indicate that:

- Surgeons may offer urethral dilation, direct visual internal urethrotomy, or urethroplasty for the *initial* treatment of a short (<2cm) bulbar urethral stricture. (Conditional Recommendation; Evidence Level: Grade C)

- Surgeons should offer urethroplasty, instead of repeated endoscopic management for recurrent anterior urethral strictures following failed dilation or direct visual internal urethrotomy. (Moderate Recommendation; Evidence Level: Grade C)
- Surgeons may offer urethral dilation or direct visual internal urethrotomy, combined with drug-coated balloons, for recurrent bulbar urethral strictures < 3 cm in length. (Conditional Recommendation; Evidence Level: Grade B).
- The use of drug-coated balloons is restricted to recurrent bulbar urethral strictures as the efficacy of repeated use of drug coated balloons has not been ascertained and is therefore not recommended.

European Association of Urology

In 2023, the European Association of Urology (EAU) updated recommendations for urethral strictures included drug-coated balloon dilation. Careful clinical review and prospective data collection, ideally part of a post marketing registry or clinical trial, is advised if drug-coated balloon dilation is the method of treatment.

EAU reported the following:

- 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. (Level of Evidence: 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)

National Institute for Health and Care Excellence

In 2021, the National Institute for Health and Care Excellence (NICE) issued a Medtech innovation briefing on Optilume for anterior urethral strictures indicating that the technology is not yet used in the National Health Service (NHS). There are indications that the manufacturer is communicating with NHS trusts and consultant urologists about adopting Optilume as part of their standard urethral stricture procedure. The manufacturer is promoting the stance that adopting the technology will require minimal additional training and can be used in existing endoscopy settings. Manufacturer opinions indicate that Optilume could reduce the need for retreatments because urethral stricture is less likely to recur. It also claims that using the technology could be resource releasing in the National Health Service because of reduced bed days, operating theatre time, use of general anesthesia, clinic appointments and ongoing treatments.

In 2022, NICE updated its recommendations to include Optilume as an option to treat bulbar urethral strictures in adults only if comparative data is collected on: (1) patient reported outcome measures and (2) reintervention rates. NICE indicated the intended use is as a second-line treatment for urethral strictures in people who have had at least 1 previous endoscopic procedure that has failed for urethral strictures ≤ 3 cm in length. The technology is used by trained consultants in urology, urology trainees and urology nurse specialists. It can be done using local anesthesia as a day case or in an outpatient setting. Key concerns revolving around the evidence or technology are that there are no comparative studies, and longer-term evidence (up to 5 years) is needed for Optilume, including the effect of paclitaxel on the tissues.

Government Regulations

National:

No determination was found regarding drug-coated balloon therapy for urethral strictures.

Local:

No determination was found regarding drug-coated balloon therapy for urethral strictures.

(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

N/A

References

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3. Labordie Medical Technologies. "Optilume® Urethral Drug Coated Balloon for the treatment of Anterior Urethral Stricture." 2025. https://www.laborie.com/product/optilume-drug-coated-balloon-for-urethral-stricture-treatment/?_gl=1*1y02bnz*_ga*NjUzMjUyOTQ0LjE2OTc2NTczNDc.*_up*MQ. Accessed March 4, 2025.
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7. Shetty.S. Bhat, S. Choudhary, A. et al. "Prevalent Practices in Male Anterior Urethral Stricture Management: A Survey." *The Open Urology & Nephrology Journal*. 2022, Volume 15.
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https://www.accessdata.fda.gov/cdrh_docs/pdf21/P210020B.pdf. Accessed March 4, 2025.
10. VanDyke ME, Morey AF, Coutinho K, et al. “Optilume drug-coated balloon for anterior urethral stricture: 2-year results of the ROBUST III trial.” *BJUI Compass*. 2023 Dec 18;5(3):366-373. PMID: 38481667.
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13. Wessells H, Morey A, Vanni A, et al. “Urethral Stricture Disease: American Urological Association Guideline.” 2023. <https://www.auanet.org/guidelines-and-quality/guidelines/urethral-stricture-guideline>. Accessed March 4, 2025.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through March 4, 2025, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
7/1/25	4/21/25		Joint policy established (slp) Vendor managed: N/A

Next Review Date: 2nd Qtr, 2026

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: DRUG COATED BALLOON FOR URETHRAL STRICTURES (I.E. OPTILUME)

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered with criteria
BCNA (Medicare Advantage)	Refer to Medicare Determination
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.