Policy Number	**SUR710.026**
Policy Effective Date	**01/01/2026**

Drug-Coated Urethral Balloon for Obstructive Urinary Symptoms

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Related Policies (if applicable)
None

Disclaimer

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

Coverage

The use of a drug-coated urethral balloon (e.g., Optilume® Urethral Drug Coated Balloon, Optilume® BPH Catheter System) **is considered experimental, investigational and/or unproven** for the treatment of obstructive urinary symptoms associated with benign prostatic hyperplasia and/or urethral stricture.

Policy Guidelines

None.

Description

Drug-coated Urethral Balloon Devices
Recently there has been interest regarding the use of a drug-coated urethral balloon to treat obstructive urinary symptoms associated with urethral stricture or benign prostatic hyperplasia.

These catheter-based devices act as a device/drug combination product. First, the device via a catheter dilates the urethra, then when the drug coated balloon is inflated it deposits a drug coating that consists of the active pharmaceutical ingredient paclitaxel. Several studies in animal models have also shown that paclitaxel applied locally inhibits smooth muscle cell and fibroblast proliferation and migration. Based on these animal models, it is thought that the urethral balloon application of paclitaxel may help maintain patency following the procedure. (1-3)

Benign Prostatic Hyperplasia (BPH)

Up to 50% of men over the age of 50 and up to 80% of men over the age of 80 experience lower urinary tract symptoms from BPH. (4) An enlarged prostate gland can block the flow of urine. As the gland enlarges it presses against the urethra making the diameter of the urethra smaller and possibly decreasing the ability to completely empty the bladder, this in turn can cause other urinary tract issues. Some of the following symptoms associated with BPH include: urinary frequency, trouble starting a urine stream, urinary retention, urinary incontinence, urinary tract infections, and possible bladder and kidney damage. The prevalence of BPH and lower urinary tract issues rises markedly with increased age.

Urethral Strictures

Urethral strictures (a narrowing of the urethral tube) are often caused by infections, trauma, and other medical procedures that injure the lining of the urethra. Urethral strictures typically develop slowly and result in a progressive narrowing of the urethral lumen. Symptoms are similar to those usually associated with bladder outlet obstruction from benign prostatic hyperplasia. Minimally invasive treatment options for urethral strictures may include dilation and endoscopic urethrotomy. Another treatment option for urethral stricture is an open surgical procedure called urethroplasty; it is noted to have better success rate however, it may require a longer recovery and possible side effects.

Regulatory Status

<u>Optilume® Urethral Drug Coated Balloon for Anterior Urethral Stricture</u>

The Optilume® Drug Coated Balloon is inserted with the aid of a cystoscope. The device is a small, cylindrical balloon coated with paclitaxel, it is positioned across the stricture, inflated to both open/dilate the urethra and allow drug penetration to the area with the stricture. The balloon is then deflated and removed. Paclitaxel has been reported to inhibit smooth muscle cell and fibroblast proliferation and may result in the inhibition of scar tissue formation and therefore stricture recurrence. (2)

In December 2021, the U.S. Food and Drug Administration (FDA) approved Optilume® Urethral Drug Coated Balloon (DCB) through the premarket approval application (PMA) process to treat 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. (2)

<u>Optilume® BPH Catheter System</u>

The Optilume BPH Catheter System is a combination drug/device product consisting of two catheters. One catheter is for pre-dilation and is a non-drug coated catheter. The other catheter, the Optilume BPH prostatic dilation DCB catheter is a drug (paclitaxel) coated catheter that further dilates and transfers the drug to the prostatic urethra and anterior commissure. The catheters are inserted through a cystoscope. Once the catheter is in place, the balloon is expanded and releases the drug into the pre-dilated prostatic urethra and prostate. After the drug coating on the balloon is fully released, the balloon is deflated and removed. (5)

In June 2023, the FDA approved the Optilume® BPH Catheter System through the PMA process with the following indications: "This device is indicated for the treatment of obstructive urinary symptoms associated with Benign Prostatic Hyperplasia (BPH) in men ≥ 50 years of age." Product Code QXB. (3)

Rationale

This medical policy is based on professional society guidelines.

American Urological Association

Management of Lower Urinary Tract Symptoms (LUTS) Secondary to Benign Prostatic Hyperplasia

In 2023, the American Urological Association (AUA) Guideline addressed effective evidence-based management of male LUTS attributed to prostatic hyperplasia (BPH). (6) The guideline sought to improve the clinicians' ability to evaluate and treat patients with BPH/LUTS based on available evidence. The authors noted that many promising surgical alternatives are in development, including prostatic stents, temporary implantable prostatic devices (TIPD), drug eluting catheters, balloon dilation devices, and transurethral prostatic split techniques to name a few. Additionally, the authors remarked that it is the hope of this Panel that further robust data will be available in the peer reviewed literature on these therapies to allow incorporation into future iterations of this guideline. The guidelines remark that to guarantee that newer technologies genuinely deliver enhanced improvements and outcomes for patients, it is crucial to maintain an ongoing benchmarking process that consistently compares new technologies to established technologies.

Urethral Stricture Disease

In 2023, the AUA Guideline on Urethral Stricture Disease published in 2016 was amended. The guideline provides evidence-based guidance on how to recognize the signs and symptoms of a urethral stricture/stenosis, appropriate testing to determine the location and severity of the stricture, and available treatment options. (7) Drug-coated balloons are addressed by Recommendation 11b: Surgeons may perform 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). Further information in the guideline addresses the ROBUST III multicenter randomized controlled trial (RCT) that compared endoscopic treatment combined with paclitaxel coated urethral balloon versus direct visual internal urethrotomy (DVIU)/dilation in patients with recurrent anterior urethral strictures <3 cm in length. Those who underwent endoscopic treatment combined with drug

coated balloon had improved freedom from intervention at 1 year compared to DVIU/dilation alone (83.2% versus 21.7%). The 3-year outcomes for the same drug-coated balloon from the Robust I trial demonstrated a 67% functional success. The document notes that although drug-coated balloons are approved by the FDA for anterior urethral strictures, the trial was not powered to assess results in patients with penile urethra strictures; therefore, the AUA recommends that drug-coated balloons are restricted to treat patients with recurrent bulbar urethral strictures. Furthermore, the efficacy of repeated use of the drug-coated balloon has not been ascertained and is not recommended.

Coding

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

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

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

CPT Codes	52284, 52443, 0619T, [Deleted 1/2024: 0499T]
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

References

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2. U.S. Food and Drug Administration. Optilume® Urethral Drug Coated Balloon (P210020) December 3, 2021. Available at: <https://www.accessdata.fda.gov> (accessed October 5, 2025).
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4. Lokeshwar SD, Harper BT, Webb E, et al. Epidemiology and treatment modalities for the management of benign prostatic hyperplasia. Transl Androl Urol. Oct 2019; 8(5):529-539. PMID 31807429
5. U.S. Food and Drug Administration. Optilume® BPH Catheter System. (P220029) Summary of Safety and Effectiveness data (SSED). June 30, 2023. Available at: <https://www.accessdata.fda.gov> (accessed October 5, 2025).
6. Sandhu JS, Bixler BR, Dahm P, et al. Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia (BPH): AUA Guideline Amendment 2023. J Urol. Jan 2024; 211(1):11-19. PMID 37706750
7. Wessells H, Morey Allen, Souter L, et al. Urethral Stricture Disease Guideline Amendment (2023). J Urol. Jul 2023; 210(1):64-71. PMID 37096574

Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

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

Policy History/Revision

Date	Description of Change
01/01/2026	Document updated. The following change was made to the Coverage: Removed "all indications including but not limited to" from the experimental, investigational and/or unproved statement. Added references 4-7; others removed.
06/15/2024	Document updated with literature review. The following change was made to the Coverage: Editorial changes were made and examples of other indications were added to the experimental, investigational and/or unproven statement; intent unchanged. References 3, 10-12 added, one reference removed. Title changed from: Optilume (Drug Coated Balloon) for the Treatment of Urethral Stricture Conditions.
05/01/2023	Document updated with literature review. Coverage unchanged. Added references 2, 5, 8-9; one reference updated.
12/01/2022	Reviewed. No changes.
01/01/2022	Document updated with literature review. Coverage unchanged. Added references 3-5.
01/15/2021	Reviewed. No changes.
03/15/2020	Document updated with literature review. Coverage unchanged. Added reference 2.
10/15/2018	Reviewed. No changes.
01/01/2018	New medical document. The use of Optilume™ (a drug coated balloon [DCB]), is considered experimental, investigational and/or unproven for all indications including but not limited to the treatment of urethral stricture conditions.