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MEDICAL POLICY – 7.01.183

Urethral Drug-Coated Balloon for Urethral Stricture and Benign Prostatic Hyperplasia

BCBSA Ref. Policy:	7.01.183
Effective Date:	**Feb. 5, 2027**
Last Revised:	Oct. 13, 2026
Replaces:	N/A

RELATED MEDICAL POLICIES:

2.01.544	Transurethral Water Vapor Thermal Therapy and Transurethral Water Jet Ablation for Benign Prostatic Hyperplasia
7.01.55	Prostate Artery Embolization for Benign Prostatic Hyperplasia
7.01.175	Temporarily Implanted Nitinol Device (iTind) for Benign Prostatic Hyperplasia
7.01.181	Permanently Implanted Prostatic Devices for Benign Prostatic Hyperplasia
7.01.598	Prostatic Urethral Lift

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RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

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Introduction

Urethral strictures occur when scar tissue narrows the tube that carries urine out of the body (urethra). This narrowing can make it hard to urinate and may cause other urinary symptoms. Some strictures come back after treatment with procedures that widen or cut the narrowed area. The Optilume urethral drug-coated balloon is a device that combines balloon dilation with a medication designed to help keep the urethra open after treatment. It is used in certain adults with recurrent narrowing of the bulbar portion of the urethra (bulbar urethral stricture). This policy describes when the Optilume urethral drug-coated balloon may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Procedure	Medical Necessity
Optilume urethral drug-coated balloon for recurrent urethral stricture	**The Optilume urethral drug-coated balloon may be considered medically necessary for the treatment of recurrent bulbar urethral stricture in adult men when all of the following criteria are met:** • The stricture is located in the bulbar urethra **AND** • The stricture is 3 cm or less in length **AND** • The stricture is recurrent, having failed prior endoscopic treatment (direct visual internal urethrotomy or dilation)

Procedure	Investigational
Optilume urethral drug-coated balloon in other circumstances	**The Optilume urethral drug-coated balloon is considered investigational for the treatment of anterior urethral stricture in all other circumstances, including but not limited to penile urethral stricture, first-time (primary) treatment, and repeated use of the device.**
Optilume BPH Catheter System	**The Optilume BPH Catheter System is considered investigational for the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia (BPH).**

Documentation Requirements
The patient's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following: • Office visit notes that contain the relevant history and physical that describe the Optilume urethral drug-coated balloon is being used to treat recurrent bulbar urethral stricture. **AND** • The stricture is 3 cm or less in length. **AND** • The prior treatment that has failed to treat the condition.

Coding

Code	Description
CPT	
52284	Drug delivery using a drug-coated balloon for male treatment of urethral stricture using an endoscope
52443	Cystourethroscopy with initial transurethral anterior prostate commissurotomy with a nondrug-coated balloon catheter followed by therapeutic drug delivery into the prostate by a drug-coated balloon catheter, including transrectal ultrasound and fluoroscopy, when performed
HCPCS	
C1889	Implantable/insertable device, not otherwise classified

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Related Information

N/A

Evidence Review

Description

Urethral stricture disease is a fibrotic narrowing of the urethral lumen, most commonly involving the anterior (bulbar) urethra, which obstructs urine flow and produces obstructive lower urinary tract symptoms (LUTS). Endoscopic treatments, namely direct visual internal urethrotomy (DVIU) and dilation, are minimally invasive but carry high recurrence rates, whereas urethroplasty is the definitive, reference-standard surgical repair. Benign prostatic hyperplasia (BPH) is a nonmalignant enlargement of the prostate that causes bladder outlet obstruction and LUTS;

management ranges from pharmacotherapy through minimally invasive surgical therapies (MISTs) to transurethral resection of the prostate (TURP).

The Optilume drug-coated balloon (DCB) platform (Urotronic, Inc., now part of Laborie) combines mechanical balloon dilation with localized delivery of paclitaxel, an antiproliferative agent intended to inhibit the fibroblastic and collagen-remodeling response responsible for re-narrowing after dilation. Two related products are addressed in this review: the Optilume Urethral DCB, for adult men with anterior urethral stricture; and the Optilume BPH Catheter System, a double-lobe DCB that performs an anterior commissurotomy while delivering paclitaxel to the prostatic urethra, for LUTS secondary to BPH.

Background

Benign Prostatic Hyperplasia

Benign prostatic hyperplasia (BPH) is a common disorder of aging men that arises from hyperplastic nodules in the transition zone and periurethral region of the prostate. Prostatic enlargement can produce bladder outlet obstruction and lower urinary tract symptoms (LUTS), which encompass voiding symptoms (weak stream, hesitancy, straining, intermittency, and incomplete emptying) and storage symptoms (urinary frequency, urgency, and nocturia). The histologic prevalence of BPH increases with age, affecting roughly half of men in their seventh decade and the large majority by their ninth decade, with symptomatic LUTS increasing in parallel. Because LUTS are nonspecific, other contributors, including overactive bladder, urethral stricture, and prostate cancer, should be excluded before symptoms are attributed to BPH.

Symptom severity is quantified using the American Urological Association Symptom Index (AUA-SI) and the International Prostate Symptom Score (IPSS). The AUA-SI is a self-administered 7-item questionnaire scored from 0 to 35, with severity categorized as mild (≤7), moderate (8–19), or severe (20–35); the IPSS incorporates the same items and adds a disease-specific quality-of-life ("bother") question.

Management is stepwise. Lifestyle and behavioral measures apply to all patients; men with bothersome moderate-to-severe symptoms are candidates for pharmacotherapy. Alpha-1 adrenergic antagonists (e.g., alfuzosin, doxazosin, silodosin, tamsulosin, terazosin) are first-line agents because they relieve symptoms within days and are well tolerated. 5-alpha-reductase inhibitors (finasteride, dutasteride) are added when the prostate is enlarged (generally >30 g) to reduce prostatic volume and slow disease progression. Additional options, used alone or in

combination, include phosphodiesterase-5 inhibitors (e.g., tadalafil) for men with concomitant erectile dysfunction and beta-3 adrenergic agonists or antimuscarinics for a predominant overactive-bladder component.

Surgical or procedural therapy is indicated for men whose symptoms are refractory to or intolerant of medical therapy, or who develop BPH-related complications such as refractory urinary retention, recurrent urinary tract infection or bladder stones, gross hematuria, or renal insufficiency. Transurethral resection of the prostate (TURP) is the long-standing reference standard against which BPH procedures are compared. A range of minimally invasive surgical therapies (MISTs)—including prostatic urethral lift (UroLift), water vapor thermal therapy (Rezūm), temporarily implanted nitinol devices (e.g., iTIND), Aquablation, and prostatic artery embolization—have been developed to reduce procedure-related morbidity and preserve sexual function relative to TURP. The Optilume BPH Catheter System is a drug/device MIST evaluated within this policy.

Anterior Urethral Stricture

A urethral stricture is a fibrotic narrowing of the urethral lumen caused by scarring of the surrounding corpus spongiosum (spongiofibrosis). The male urethra is divided into the anterior urethra (the meatus, fossa navicularis, pendulous [penile] urethra, and bulbar urethra) and the posterior urethra (the membranous urethra, prostatic urethra, and bladder neck). Because spongiofibrosis can extend beyond the visible mucosal narrowing, the functional stricture length may exceed that seen on endoscopy or imaging. This policy concerns anterior, predominantly bulbar, strictures, the segment most relevant to the interventions under review.

Urethral stricture disease is relatively common, affecting on the order of 0.5% of males over a lifetime. Etiology varies by setting; in resource-abundant countries the most frequent causes are idiopathic and iatrogenic, the latter including transurethral instrumentation, prior endoscopic prostate surgery, and traumatic catheter placement, which together account for a large proportion of cases. Other causes include external (e.g., straddle) trauma, infection, lichen sclerosus, and pelvic radiation. Because the interval between an inciting event and symptomatic presentation is often long, the etiology frequently remains unknown.

Most patients present with chronic obstructive voiding symptoms such as a weak stream and incomplete emptying; others present with recurrent urinary tract infection, urinary spraying, dysuria, ejaculatory changes, or, less commonly, acute urinary retention. Noninvasive studies (uroflowmetry and post-void residual measurement) suggest obstruction but cannot localize it

or distinguish urethral from prostatic causes; definitive diagnosis and characterization of stricture location, length, and severity require cystourethroscopy and/or urethral imaging (retrograde urethrogram, voiding cystourethrogram, or ultrasound urethrography).

Treatment is individualized to stricture length, location, severity, and etiology. Endoscopic options, urethral dilation and direct vision internal urethrotomy (DVIU), are minimally invasive and widely available but carry high recurrence rates (reported from approximately 30% to 80%), particularly for recurrent or longer strictures. Current guidelines therefore recommend no more than a single endoscopic attempt for short (<2 cm) bulbar strictures and advise against repeated endoscopic treatment, which can lengthen and complicate the disease and make eventual reconstruction more difficult. Urethroplasty (open surgical reconstruction) is the reference standard for recurrent, long, penile, or posterior strictures, with reported success rates of roughly 80% to 95%, but it is more invasive and less widely performed. Urinary diversion (e.g., perineal urethrostomy or suprapubic catheter) is reserved for men who are medically unfit for or wish to avoid reconstruction. Pharmacologic adjuncts to DVIU (e.g., mitomycin C, corticosteroids) have shown variable benefit. The 2023 amendment to the AUA urethral stricture guideline incorporated drug-coated balloon dilation as a treatment option for recurrent anterior urethral stricture.

Optilume Drug-Coated Balloon Platform

The Optilume platform (Urotronic, Inc.) applies paclitaxel-coated balloon (DCB) technology—combining mechanical dilation with local delivery of the antiproliferative, antifibrotic agent paclitaxel; to two distinct urologic indications. The shared rationale is that paclitaxel, transferred circumferentially to the treated tissue at the time of dilation, inhibits the fibroblast proliferation and scar re-formation that drive recurrence after mechanical treatment alone.

Optilume Urethral Drug-Coated Balloon

For urethral stricture, the Optilume urethral DCB is a dual-lumen, over-the-wire balloon catheter whose semi-compliant balloon is coated with paclitaxel along its working length. After the strictured segment is dilated (typically following predilation), the balloon is expanded to exert radial force and transfer paclitaxel to the urethral wall, with the intent of maintaining luminal patency and reducing stricture recurrence. Its pivotal evidence base comprises the single-arm

ROBUST I study and the randomized ROBUST III trial in men with recurrent anterior (bulbar) urethral strictures.

Optilume BPH Catheter System

For BPH, the Optilume BPH Catheter System comprises an uncoated pre-dilation catheter and a double-lobe, paclitaxel-coated dilation balloon. Mechanical dilation produces an anterior commissurotomy, separating the lateral prostatic lobes, while paclitaxel is delivered locally to limit lobe re-fusion and maintain luminal patency during healing. It is positioned as a minimally invasive surgical therapy that requires no cutting, ablation, or permanent implant, and is performed transurethrally in an outpatient setting. Its pivotal evidence base comprises the randomized, double-blind, sham-controlled PINNACLE trial and the single-arm EVEREST program.

Summary of Evidence

For individuals with recurrent anterior (bulbar) urethral stricture ≤3 cm who have failed prior endoscopic treatment and who receive the Optilume urethral drug-coated balloon, the evidence includes 1 pivotal multicenter RCT (ROBUST III), 2 prospective single-arm studies (ROBUST I and ROBUST II), and one systematic review. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, sexual function, treatment-related morbidity, and long-term device complications. ROBUST III met its prespecified 6-month anatomic primary endpoint against endoscopic management and showed durable freedom from repeat intervention through 3 years, with concordant symptomatic and functional improvement in the single-arm studies, although objective flow measures attenuated over time. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with moderate-to-severe lower urinary tract symptoms secondary to benign prostatic hyperplasia who receive the Optilume BPH Catheter System, the evidence includes 1 sham-controlled RCT (PINNACLE) with within-arm follow-up to 2 years and 1 single-arm feasibility cohort (EVEREST-I) with follow-up to 4 years. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, sexual function, treatment-related morbidity, and long-term device complications. PINNACLE met simple superiority over sham on its primary IPSS comparison but did not maintain significance under its prespecified 25% super-superiority margin, used an asymmetric primary comparison (Optilume at 12 months vs sham at

3 months), and provides no head-to-head comparison against other minimally invasive surgical therapies; durability data are within-arm in a selected population. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing trials that might influence this review are listed in **Table 1**.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05383274[a]	Optilume Post-Approval Clinical Evaluation of Andrology Parameters (anterior urethral stricture)	34	Jun 2026
NCT05479422	European Clinical Registry for the Optilume Urethral Drug-Coated Balloon (anterior urethral stricture)	150	Aug 2029
NCT06795074	Recurrent Urethral Stricture After Optilume vs a Non-Coated Dilatation Balloon: a Prospective Randomized Multicenter Study	230	Feb 2029
NCT06827210	Treatment of Bulbar Urethral Strictures With Optilume vs Standard DVIU in an Untreated Population	140	Jan 2027
NCT06769997	The Optizum Study: Optilume BPH Catheter System vs Rezum Water Vapor Therapy for BPH	100	Jan 2027
NCT06560476[a]	Prospective Multi-site Registry of Real-World Experience With the Optilume BPH Catheter System	500	Mar 2027
NCT06312722[a]	Safety and Effectiveness of the Optilume BPH Catheter System in a Post-Market Study	92	Feb 2031

BPH: benign prostatic hyperplasia; DVIU: direct visual internal urethrotomy; NCT: national clinical trial. [a] Denotes industry-sponsored or cosponsored trial.

Practice Guidelines and Position Statements

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

Guidelines or position statements will be considered for inclusion 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

The American Urological Association (AUA) addressed the Optilume urethral drug-coated balloon in its Urethral Stricture Disease Guideline Amendment (2023).[21] Citing the ROBUST III randomized trial (freedom from repeat intervention 83.2% vs 21.7% at 1 year) and the ROBUST I 3-year functional-success rate of 67%, the panel issued a conditional recommendation that use of a drug-coated balloon be restricted to men with recurrent bulbar urethral strictures. Because the pivotal trial was not powered to assess penile urethral strictures (approximately 10% of the cohort), the recommendation does not extend to penile strictures; drug-coated balloons were not assessed in controlled trials for first-time treatment of anterior urethral stricture, and repeated use of the device is not recommended.

In 2026, the AUA published a three-part guideline on the Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia.[22] Part III addresses procedural and surgical management and is informed by a systematic review with literature searches through January 2025 and an update search conducted December 15, 2025. This guideline addresses the Optilume BPH Catheter System within the device category of intraprostatic drug coated balloon (IPDCB), described as a two-stage transurethral procedure employing a temporary dilating balloon followed by a paclitaxel-coated balloon. The panel stated: "Clinicians may offer intraprostatic drug coated balloon (IPDCB) as an option for patients with prostates 20-80 cc, a prostatic urethral length 32-55 mm, and without an obstructing median lobe for the treatment of LUTS/BPH. (Conditional Recommendation; Evidence Level: Grade C)."

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

In December 2021, the Optilume urethral drug-coated balloon (Urotronic, Inc.) was approved by the US Food and Drug Administration (FDA) through the premarket approval (PMA) process (P210020; product code QRH).[1] It is indicated for the treatment of obstructive urinary symptoms associated with anterior urethral stricture in adult males, with intended improvement in urinary flow rate through at least six months post-procedure.

In June 2023, the Optilume BPH Catheter System (Urotronic, Inc.) was approved by the FDA through the PMA process (P220029; product code: QXB).[2] It is indicated for the treatment of obstructive urinary symptoms associated with BPH in men aged 50 years and older.

Both devices are contraindicated in patients with known hypersensitivity to paclitaxel or structurally related compounds and in the presence of active urinary tract infection. Because paclitaxel is detectable in semen for a period after treatment, barrier contraception is advised for men whose partners may become pregnant.

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History

Date	Comments
11/01/26	New policy, approved October 13, 2026, effective for dates of service on or after February 5, 2027, following 90-day provider notification. Add to Surgery section. Policy created with literature review through June 12, 2026. The Optilume urethral drug-coated balloon may be considered medically necessary for the treatment of recurrent anterior (bulbar) urethral stricture in adult men when criteria are met. The Optilume urethral drug-coated balloon is considered investigational for the treatment of anterior urethral stricture in all other circumstances. The Optilume BPH Catheter System is considered investigational for the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia.

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