LOUISIANA BLUE

Optilume Device for Urethral Stricture and Benign Prostatic Hyperplasia

Policy # 00995
Original Effective Date: 01/01/2027
Current Effective Date: 01/01/2027

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

Note: Prostatic Urethral Lift is addressed separately in medical policy 00480.

Note: Transurethral Water Vapor Thermal Therapy (Rezum) and Transurethral Water Jet Ablation (Aquablation) for Benign Prostatic Hypertrophy is addressed separately in medical policy 00684.

Note: Temporarily Implanted Nitinol Device (iTind) for Benign Prostatic Hyperplasia is addressed separately in medical policy 00825.

Note: Prostate Artery Embolization is addressed separately in medical policy 00957.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider the Optilume Urethral drug-coated balloon (Optilume Urethral DCB) for the treatment of recurrent bulbar urethral stricture to be **eligible for coverage**** when **ALL** of the following criteria are met:

- Adult men with the stricture located in 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); **AND**
- Absence of active urinary tract infection.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the Optilume Urethral drug-coated balloon (Optilume Urethral DCB) to be **not medically necessary**** for the treatment of urethral

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stricture when criteria are not met and in all other circumstances, including but not limited to **ANY** of the following:

- Penile urethral stricture; **OR**
- Prostatic urethral stricture; **OR**
- First-time (primary) treatment; **OR**
- Repeated use of the device.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the Optilume BPH Catheter System for the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia (BPH) to be **investigational.***

Background/Overview

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 (eg, 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 (eg, 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 (eg, iTIND), aquablation, and prostatic artery embolization—has 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 (eg, 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 (eg, perineal urethrostomy or suprapubic

catheter) is reserved for men who are medically unfit for or wish to avoid reconstruction. Pharmacologic adjuncts to DVIU (eg, 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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
In December 2021, the Optilume Urethral Drug-Coated Balloon (Urotronic, Inc.) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval (PMA) process (P210020). 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). 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.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

Description

Urethral stricture disease is a fibrotic narrowing of the urethral lumen, most commonly involving the anterior (bulbar) urethra, that 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.

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.

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
The American Urological Association (AUA) addressed the Optilume Urethral drug-coated balloon in its Urethral Stricture Disease Guideline Amendment (2023). 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.

The AUA Guideline on the Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia was most recently amended in 2023, with an evidence review through October 2022. That amendment updated statements on photoselective vaporization of the prostate, water vapor thermal therapy, laser enucleation, and prostatic artery embolization, but it does not address the Optilume BPH Catheter System, which received FDA approval in June 2023 and whose pivotal RCT (PINNACLE) was published after the guideline search window. The AUA has not issued a recommendation on the Optilume BPH Catheter System.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some currently unpublished 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.

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Policy History

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10/01/2026 Medical Policy Committee review
10/07/2026 Medical Policy Implementation Committee review
10/15/2026 Medical Quality Management Committee approval. New policy.
Next Scheduled Review Date: 10/2027

Coding

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	52284, 52443
HCPCS	C1889
ICD-10 Diagnosis	N40.1-N40.3, N35.010-N35.016, N35.111-N35.119, N35.811-N35.819, N35.911-N35.919

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services

at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan’s authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan. This provision does not apply to medications covered under the plan’s pharmacy benefit.