NO. 91642-R1

BENIGN PROSTATIC HYPERPLASIA AND URETHRAL STRICTURE TREATMENTS

Effective date: 03/01/2026 **Last reviewed**: 02/2026

Instructions for use: This document is for informational purposes only. Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable. Eligibility and benefit coverage are determined in accordance with the terms of the member's plan in effect as of the date services are rendered. It is not an authorization, certification, explanation of benefits, or contract. Receipt of benefits is subject to satisfaction of all terms and conditions of coverage. Priority Health's medical policies are developed with the assistance of medical professionals and are based upon a review of published and unpublished information including, but not limited to, current medical literature, guidelines published by public health and health research agencies, and community medical practices in the treatment and diagnosis of disease. Because medical practice, information, and technology are constantly changing, Priority Health reserves the right to review and update its medical policies at its discretion. Priority Health's medical policies are intended to serve as a resource to the plan. They are not intended to limit the plan's ability to interpret plan language as deemed appropriate. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment they choose to provide.

Policy scope: This policy defines coverage criteria for the treatment of benign prostatic hyperplasia (BPH) and urethral strictures, including relevant diagnoses and medical necessity requirements.

Related policies:

- None

SUMMARY OF CHANGES – R1

Additions:

- Added Government/Regulatory sections
- Added Policy Scope section
- Updated Policy Name
- Added medical necessity criteria for mechanical urethral dilation by drug-coated balloon (Optilume)

Clarifications

- Updated background and references

I. MEDICAL NECESSITY CRITERIA

A. BPH:

1. The following approaches to the treatment of benign prostatic hypertrophy (BPH) are medically necessary:
    a. Holmium Laser Enucleation of the Prostate (HoLEP), Thulium laser enucleation of the prostate (ThuLEP)
    b. Simple prostatectomy (Open, laparoscopic, or robotic assisted) when InterQual criteria are met.
    c. Photoselective vaporization of the prostate (PVP)
    d. Transurethral incision of the prostate (TUIP)
    e. Transurethral resection of the Prostate (TURP)
    f. Transurethral vaporization of the prostate (TUVP)

2. Prostatic Artery Embolization

    PAE may be medically necessary for benign prostatic hyperplasia (BPH) when **all** of the following are met:

    a. Evaluation and referral by a urologic surgeon
    b. Moderate to severe lower urinary tract symptoms (LUTS)
    c. Refractory to at least 6 months of medical therapy
    d. Prostate volume too large (>80 cc) for transurethral procedure
    e. Poor surgical candidate for open prostatectomy
    f. Prostate Specific Antigen (PSA) <2.5 ng/mL, or PSA >2.5 ng/mL *and* ≤10 ng/mL AND free PSA > 25% of total PSA

    Prior authorization for imaging prior to PAE is required. A computed tomographic angiography (CTA) of the pelvis is medically necessary for PAE when indicated if the above criteria are met.

    PAE is not considered medically necessary if any of the following are present:

    g. Active prostatitis or urinary tract infection
    h. Cystolithiasis within the past 3 months
    i. History of prior pelvic irradiation
    j. History of prostate, bladder, or rectal cancer
    k. History of transurethral resection of the prostate (TURP), open prostate surgery, or radiofrequency or microwave therapies of prostate
    l. Serum creatinine values >1.7mg/dl or glomerular filtration rates less than 50
    m. Confounding bladder or urethral conditions (e.g. neurogenic bladder, urethral stricture)

    PAE for all other conditions is considered experimental and investigational and/or not medically necessary.

3. Prostatic Urethral Lift
    a. The UroLift System is medically necessary for the treatment of symptomatic benign prostatic hypertrophy (BPH), including lateral and median lobe hyperplasia, when both of the following criteria are met:
        i. Men age 45 and older, and

ii. Prostate volume < 100 cc

b. UroLift is not medically necessary if *any* of the following are present:
   i. Active urinary tract infection
   ii. Gross hematuria
   iii. Prostate volume of >100 cc
   iv. Urethral conditions that may prevent insertion of delivery system into bladder
   v. Urinary incontinence due to incompetent sphincter

c. Coverage is limited to a maximum of seven (7) implants.

4. The Rezūm System
   a. The Rezūm System is medically necessary for the reduction of prostate tissue associated with BPH, and for treatment of prostate with hyperplasia of the central zone and/or a median lobe when both of the following criteria are met:
      i. Men age 50 and older, and
      ii. Prostate volume ≥ 30 cc and ≤ 80 cc
      iii. The Rezūm System is not indicated for patients with a urinary sphincter implant or penile prosthesis.

5. Transurethral Waterjet Ablation
   a. Transurethral Waterjet Ablation of the prostate for the treatment of LUTS/BPH will be considered medically necessary when all of the following are met:
      i. Prostate volume of 30-150 cc transrectal ultrasound (TRUS)
      ii. Persistent moderate to severe symptoms despite maximal medical management including ALL of the following:
         i. International Prostate Symptom Score (IPSS) ≥12
         ii. Maximum urinary flow rate (Qmax) of ≤15 mL/s (voided volume greater than 125 cc)
         iii. Failure, contraindication or intolerance to at least three months of conventional medical therapy for LUTS/BPH (e.g., alpha blocker, PDE5 Inhibitor, finasteride/dutasteride)
         iv. Device must be FDA approved or cleared device

   b. Transurethral waterjet ablation of the prostate is not considered medically necessary if any of the following are present:
      i. Body mass index ≥ 42kg/m2
      ii. Known or suspected prostate cancer (based on NCCN Prostate Cancer Early Detection guidelines) or a prostate specific antigen (PSA) >10 ng/mL unless the member has had a negative prostate biopsy within the last 6 months.
      iii. Bladder cancer, neurogenic bladder, bladder calculus or clinically significant bladder diverticulum
      iv. Active urinary tract or systemic infection
      v. Treatment for chronic prostatitis

vi. Diagnosis of urethral stricture, meatal stenosis, or bladder neck contracture
vii. Damaged external urinary sphincter
viii. Known allergy to device materials
ix. Inability to safely stop anticoagulants or antiplatelet agents preoperatively.

6. The following approaches for the treatment of BPH experimental or investigational and unproven, or not medically necessary because the clinical effectiveness has not been established by the peer-reviewed medical literature:
   a. Optilume drug coated balloon for BPH
   b. Permanent urethral stent (UroLume endourethral prosthesis)
   c. Transrectal thermal therapy
   d. Transurethral microwave thermotherapy (TUMT)
   e. Transurethral needle ablation of the prostate (TUNA)
   f. Temporary implanted prostatic devices (i.e. temporary prostatic stents, Spanner)

B. Urethral Stricture:

A. Cystourethroscopy with mechanical urethral dilation and urethral therapeutic drug delivery by drug-coated balloon (Optilume) catheter for **recurrent** bulbar strictures is considered medically necessary when ***all*** of the following criteria are met:
   1. Member has had at least **two** failed prior attempts at urethral dilation.
   2. Member has **recurrent bulbar urethral stricture <3cm** in length

II. CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) COVERAGE DETERMINATION

Any applicable federal or state mandates will take precedence over this medical coverage policy.

Medicare: Refer to the CMS Online Manual System (IOMs) and Transmittals.
For the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA) refer to CMS Medicare Coverage Database.

The information below is current as of the review date for this policy. However, the coverage issues and policies maintained by CMS are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. MAC jurisdiction for purposes of local coverage determinations is governed by the geographic service area where the Medicare Advantage plan is contracted to provide the service. Please refer to the Medicare Coverage Database website for the most current applicable NCD, LCD, LCA, and CMS Online Manual System/Transmittals.

National Coverage Determinations (NCDs)	
None	
Local Coverage Determinations (LCDs)	
CGS Administrators, LLC	LCD - Laser Ablation of the Prostate (L34090)
First Coast Service Options, Inc.	None identified
National Government Services, Inc.	LCD - Fluid Jet System Treatment for LUTS/BPH (L38367)

Noridian Healthcare Solutions	None identified
Novitas Solutions, Inc.	None identified
Palmetto GBA	None identified
WPS Insurance Corporation	None identified

III. BACKGROUND

Benign prostatic hyperplasia (BPH) is a non-cancerous enlargement or growth of the prostate. As the prostate enlarges, the gland presses against and pinches the urethra and the bladder wall becomes thicker. Eventually, the bladder may weaken and lose the ability to empty completely, leaving some urine in the bladder. The narrowing of the urethra and urinary retention—the inability to empty the bladder completely—cause many of the problems associated with benign prostatic hyperplasia. The cause of benign prostatic hyperplasia is not well understood; however, it occurs mainly in older men (NIDKK, 2014).

Holmium Laser Enucleation (HoLEP) and Thulium Laser Enucleation (ThuLEP)

Endoscopic enucleation of the prostate (EEP) is a method of removing excess prostate tissue that contributes to BPH symptoms. Several energy sources have been used to aid enucleation, including holmium:yttrium-aluminum-garnet (Ho:YAG), thulium:YAG (Thu:YAG), and other lasers, as well as monopolar and bipolar electrocautery. Ho:YAG and Thu:YAG lasers remain among the energy sources most commonly applied for EEP.

Holmium laser enucleation of the prostate (HoLEP) was initially described by Gilling et al in 1998. The energy of the Ho:YAG laser is transmitted in pulses, creating a steam bubble at the tip of the laser fiber, which aids mechanical dissection. HoLEP has been proven to be at least equivalent to TURP in terms of improving (LUTS) and voiding parameters while being superior in the amount of tissue removed. In comparison to open prostatectomy, the rate of transfusion, hemoglobin loss, length of stay (LOS), and catheter time are reduced, while improvements in the maximum flow rate (Qmax) and LUTS are comparable. The Thu:YAG laser transmits energy as a continuous wave. Its wavelength is close to 2.0 µm, the peak for water absorption, which thus facilitates vaporization and cutting. Thulium laser enucleation of the prostate (ThuLEP) was described by Herrmann et al in 2010 as an evolution of thulium laser vapoenucleation of the prostate (ThuVEP) described by Bach et al in 2009. In theory, ThuLEP uses blunt dissection to a greater extent than ThuVEP, where mainly the incising capacity of the laser is utilized. In clinical practice, a combination of the two techniques is usually performed and a clear distinction is not feasible. The cutting ability may be advantageous in situations in which the enucleation plane cannot easily be entered, as anatomical enucleation is not strictly necessary. By contrast, HoLEP is generally considered to be more anatomical, as the mechanical energy of the laser tends to follow the path of least resistance, which is usually the plane between the adenoma and the surgical capsule.

In a meta-analysis by Hartung et al (2021) comparing HoLep versus ThuLEP, the authors found that both treatments offer comparable improvement in symptoms and postoperative voiding parameters. Both procedures are safe and major complications are rare. ThuLEP showed minor advantages for blood loss and the incidence of transient incontinence. Treatment choice should be based on surgeon expertise and local conditions.

Guidelines:
American Urological Association - *Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia (BPH): AUA Guideline Amendment 2023*

- "Holmium laser enucleation of the prostate (HoLEP) or thulium laser enucleation of the prostate (ThuLEP) should be considered as an option, depending on the clinician's expertise with these techniques, as prostate size-independent options for the treatment of LUTS/BPH. (Moderate Recommendation; Evidence Level: Grade B)" (Sandhu et al, 2023)

European Association of Urology - *Non-Neurogenic Male Lower Urinary Tract Symptoms (LUTS) (2024)*

- "Offer laser enucleation of the prostate using Ho:YAG laser (HoLEP) to men with moderate-to-severe LUTS as an alternative to transurethral resection of the prostate or open prostatectomy [strength rating: strong]"
- "Offer enucleation of the prostate using the Tm:YAG laser (ThuLEP, ThuVEP) to men with moderate-to-severe LUTS as an alternative to transurethral resection of the prostate, holmium laser enucleation or bipolar transurethral (plasmakinetic) enucleation [strength rating: weak]" (Cornu et al, 2024).

Drug Coated Balloon for BPH (i.e., Optilume)
The Optilume® BPH Catheter System (Urotronic Inc., Plymouth, Minnesota, USA) is the first prostatic drug-coated balloon dilation system for the treatment of obstructive BPH. The system combines mechanical dilation to achieve commissurotomy of the anterior prostatic urethra to open the urethral lumen, with the delivery of the drug paclitaxel to the dilated area to maintain urethral patency. Paclitaxel is an antiproliferative drug that has been extensively used in vascular devices to prevent restenosis after balloon angioplasty or stenting. The goal of this technology is to provide immediate symptomatic relief via balloon dilation and to achieve durable results via localized paclitaxel delivery. In the PINNACLE study, A total of 148 men were randomized (100 active, 48 sham) at 18 centers in the U.S. and Canada. Subjects randomized to receive Optilume BPH saw a reduction in International Prostate Symptom Score of 11.5±7.8 points at 1 year posttreatment, as compared to a reduction of 8.0±8.3 points at 3 months in the sham arm. Flow rate was dramatically improved after treatment with Optilume BPH, with an improvement of +10.3 mL/s from baseline to 1 year (+125%). (Kaplan et al., 2023). More studies evaluating long-term safety and efficacy of this treatment are needed.

Kaplan et al. (2024) conducted a randomized controlled trial (PINNACLE) evaluating two-year outcomes following treatment with the Optilume BPH Catheter System for benign prostatic hyperplasia. Of the original cohort, 77 subjects in the treatment arm were available for follow-up. At two years, 67% of participants met the response criteria (≥30% improvement without medical or surgical retreatment). Symptom scores (IPSS) improved by 50.8%, peak urinary flow (Qmax) increased by 116% (from 8.9 mL/sec to 19.0 mL/sec), and post-void residual volume showed a slight reduction. BPH Impact Index improved from 7.0 to 2.3 at one year and remained stable through two years. The most common adverse events were hematuria and urinary tract infection; no device-related or serious adverse events were reported beyond one year. Sexual function was unaffected.

The EVEREST study (2024) provides the first long-term follow-up data for patients treated with the Optilume BPH Catheter System, with outcomes assessed through four

years. Of the original 80 participants, 59 were available for follow-up. Results indicate that the significant improvements in urinary flow and symptom scores observed post-treatment were sustained over four years. Clinically meaningful improvement in IPSS was maintained in 78% of patients, with an average reduction of 12.1 points (55%) from baseline. Peak urinary flow (Qmax) remained improved, averaging 17.2 mL/sec (+5.6 mL/sec vs. baseline). No late-onset device-related complications or adverse events were reported. Limitations include the single-arm study design.

Kaur and Saini (2024) describe Optilume BPH as an innovative, minimally invasive treatment for LUTS secondary to BPH. They highlight promising outcomes from the PINNACLE Study—significant symptom relief and preserved sexual function—while emphasizing the need for long-term safety data and larger trials to confirm durability and address paclitaxel exposure concerns.

Temporary Implanted Prostatic Devices (i.e. Temporary Prostatic Stents)
Temporary implanted prostatic devices are intended to provide temporary relief from symptoms of BPH caused by prostatic obstruction. These devices include but are not limited to iTind (temporary implanted nitinol device) and The Spanner temporary prostatic stent. The iTind treatment involves insertion of a single folded device into the prostatic urethra. The device expands and exerts continuous gentle ischemic pressure on the prostatic urethra and the bladder neck over 5-7 days, causing ischemic necrosis and creating channels that allow for increased urine flow. The device is then removed in a second outpatient procedure. (Kernen et al., 2023)

The Spanner stent is mounted on an insertion device and advanced along the urethral meatus and pendulous urethra until the tip is within the bladder. The Spanner system utilizes a balloon which is then inflated with 5 mL of sterile water and seated in the bladder neck. The distal anchor is deployed distal to the external Permanent Urethral Stent (UroLume Endourethral Prosthesis) sphincter and the insertion tool is removed from the urethra. (McKenzie et al., 2011) In contrast to iTind, the Spanner can remain in place for up to 30 days before requiring removal and re-insertion. In an FDA investigational device exemption (IDE) study by Cambio and colleagues (2022), The Spanner was placed for 3 cycles of 30 days in catheter-dependent men with comorbid conditions, confirmed detrusor contractility, and catheter-associated discomfort. At each visit, postvoid residual, maximum flow rate, international prostate symptom score, quality of life, and adverse events were assessed. Voiding success was defined as PVR ≤ 150 ml at all visits. One hundred seven men were enrolled at 8 US sites; 82/107 (76.6%) completed the trial, and 79/107 (73.8%) successfully maintained PVR ≤ 150 ml for the trial duration. Patients were 77.1 ± 10.6 years old; 63/107 (58.9%) were dependent on Foley and 40/107 (37.4%) on intermittent catheterization for 36.0 ± 39.3 days and 30.2 ± 45.8 days, respectively. 25/107 (23.4%) discontinuations were primarily due to voluntary patient withdrawal 9/107 (8.4%), investigator-initiated withdrawal 8/107 (7.5%), or lack of effectiveness 4/107 (3.7%). During Spanner use, the mean Qmax was 11.2 ± 6.6, mean IPSS was 7.5 ± 6.4, and mean QOL was 2.0 ± 1.6. The most prevalent device-related adverse events were asymptomatic bacteriuria 25/107 (23.4%), discomfort 10/107 (9.4%), and urinary urgency 8/107 (7.5%). No device-related serious adverse events were reported. There is a lack of high-quality systematic reviews and meta-analyses to confirm safety and efficacy of temporary implanted prostatic devices.

Guidelines:
American Urological Association - *Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia (BPH): AUA Guideline Amendment 2023*

- "TIPD may be offered as a treatment option for patients with LUTS/BPH provided prostate volume is between 25 and 75g and lack of obstructive median lobe. (Expert Opinion)" (Sandhu et al, 2023)

Permanent Urethral Stent (UroLume Endourethral Prosthesis)
The UroLume prostatic stent is a woven tubular mesh consisting of erosion resistant wire that was designed specifically for use within the urethra. During a cystoscopy procedure, a calibrated balloon catheter is used to measure the prostatic length. Once the appropriate length is determined, the stent is deployed into the prostatic urethra and the expansile force of the mesh holds it in position. The intent of the device is that the epithelium will grow over the stent, covering it entirely while maintaining patency of the prostatic urethra. (Yip et al., 1997) The device originally received FDA approval for use in urethral strictures, and more recently approval has expanded to include BPH; however there is not sufficient evidence for safety and efficacy of this device for the indication of BPH. In a systematic review by Armitage and colleagues, a total of 20 case series were included which evaluated the UroLume stent in a total of 990 patients with benign prostatic hyperplasia. 84% who were catheter dependent voided spontaneously after stent insertion. Ten studies assessed symptoms before stent insertion and at some point within 1 year after stent insertion. All reported decreases in symptom scores, including Madsen-Iversen by 7.9 to 14.3 points and International Prostate Symptom Score by 10 to 12.4 points. Peak urine flow rates increased by 4.2 to 13.1 ml per second. A total of 104 stents (16%) failed in 606 patients who were evaluable at 1 year and migration was the commonest cause of failure (38 stents or 37%). Most patients initially experienced perineal pain or irritative voiding symptoms following stent placement. 1 of 6 men needed the UroLume removed within a year because of complications. Inadequate follow up prevented conclusions on stent durability beyond 1 year. (Armitage et al, 2007)

Photoselective Vaporization of the Prostate (PVP)
Photoselective vaporization of the prostate (PVP) with the GreenLight laser™ (GLL) (American Medical Systems, Minnetonka, USA) is a minimally invasive method of treating BPH. The first generation machines (60 W and 80 W) used a potassium-titanyl-phosphate crystal to double the frequency of a Nd:YAG laser, emitting a 532-nm wavelength, delivered to tissues by a side-firing fiber and producing a vaporization effect due to a very high absorption coefficient at this wavelength by its target chromophore that is hemoglobin molecule. This high energy density delivered to the prostatic tissue leads to rapid vaporization of the superficial tissue with a small rim of coagulated tissue. The new generation machines use a lithium-triborate crystal that allowed an increase in the maximum power output of the GLL from 80 W to 180 W. Moreover, new fibers have been introduced, resulting in even higher energy application and faster tissue vaporization via a larger laser beam area. As a result, GLL has become the preferred surgical technique to manage patients who cannot stop anticoagulation/antiplatelet therapy (Castellani et al., 2021). Meta-analyses of RCTs comparing photoselective vaporization of the prostate (PVP) using the 80- W and 120-W lasers with TURP have reported no difference in Qmax and IPSS between 80-W or 120-W PVP and TURP. Another meta-analysis of four RCTs including 559 patients, on the 120-W laser, demonstrated no significant difference in functional and symptomatic parameters at 24-month follow-up when compared to TURP. A meta-analysis of two RCTs reported similar

efficacy of 120-W PVP, compared to monopolar transurethral resection of the prostate (M-TURP) at 36- months follow-up. The only available RCT for the 180-W laser reported noninferiority to TURP in terms of IPSS, Qmax, PVR, prostate volume reduction, PSA decrease and QoL questionnaires. Efficacy outcomes were similar to TURP with stable results at 24-months follow-up (Cornu et al, 2024)

Guidelines:
American Urological Association - *Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia (BPH): AUA Guideline Amendment 2023*

- "PVP should be offered as an option using 120W or 180W platforms for the treatment of LUTS/BPH. (Moderate Recommendation; Evidence Level: Grade B)" (Sandhu et al, 2023)

European Association of Urology - *Non-Neurogenic Male Lower Urinary Tract Symptoms (LUTS) (2024)*

- "Offer 80-W 532-nm Potassium-Titanyl-Phosphate (KTP) laser vaporization of the prostate to men with moderate-to-severe LUTS with a prostate volume of 30-80 mL as an alternative to transurethral resection of the prostate (TURP) [strength rating: strong]"
- "Offer 120-W 532-nm Lithium Borat (LBO) laser vaporization of the prostate to men with moderate-to-severe LUTS with a prostate volume of 30-80 mL as an alternative to TURP. [strength rating: strong]"
- "Offer 180-W 532-nm LBO laser vaporization of the prostate to men with moderate-to-severe LUTS with a prostate volume of 30-80 mL as an alternative to TURP. [strength rating: strong]"
- "Offer laser vaporization of the prostate using 80-W KTP, 120- or 180-W LBO lasers for the treatment of patients receiving antiplatelet or anticoagulant therapy with a prostate volume < 80 mL [strength rating: weak]" (Cornu et al., 2024).

Prostatic Artery Embolization (PAE)
PAE is a minimally invasive procedure for benign prostatic hyperplasia (BPH) to improve lower urinary tract symptoms (nocturia, hesitancy, urgency, frequency, decreased urinary flow, incomplete emptying) by decreasing the prostate volume. The procedure is offered as an alternative to transurethral resection of the prostate (TURP) or open prostatectomy. PAE selectively occludes small prostatic arteries and deprives the enlarged prostate of blood supply and nutrients. This leads to ischemic necrosis and shrinkage of the affected section of the prostate gland. The procedure is performed using a percutaneous transfemoral approach by an interventional radiologist under local anesthesia and sedation. The arterial occlusion may be achieved through the use of polyvinyl alcohol particles, coil embolizers, or microspheres.

In June 2017, the FDA granted Embosphere Microspheres additional 510(k) clearance for embolization of prostatic arteries (EPA) for symptomatic benign prostatic hyperplasia (BPH), making it a prostatic artery embolization device. Embosphere Microspheres are currently indicated for use in embolization of arteriovenous malformations, hypervascular tumors, including symptomatic uterine fibroids, and prostatic arteries for symptomatic BPH.

In four RCT (Gao, 2014; Carneval, 2016; Abt 2018 Insausti 2020) studies comparing PAE to TURP found PAE was associated with statistically significant improvement in

some or all measures of LUTS and a measure of erectile function. In a RCT comparing PAE to placebo Pisco et al. (2020) found PAE is somewhat better than TURP for perioperative outcomes but consistently inferior to TURP for improving symptoms of BPH. PAE resulted in clinically significant improvement in IPSS and IPSS Quality of Life (IPSS-QoL) and statistically significant improvement in BPH Impact Index (BII), peak urinary flow, postvoid residual urine volume, prostate volume, and PSA level. In other studies comparing pretreatment with posttreatment, PAE was associated with statistically significant improvement in some or all of these outcome measures and a measure of erectile function. A systematic review and meta-analysis to evaluate PAE vs TURP for BPH (Xu, 2021) concluded that TURP is more effective than PAE for reducing prostate volume and increasing peak urinary flow but that PAE is more effective for preserving sexual function. Differences between PAE and TURP in IPSS, IPSS-QoL, PVR, PSA level, and complications were not significant.

The Society of Interventional Radiology (SIR) guidelines (McWilliams, 2019) concluded that PAE is an acceptable option for treatment of appropriately selected male persons who have BPH and moderate to severe symptom with good shortand midterm durability. The American Urological Association guidelines (Sandhu, 2023) on the management of BPH with LUTS states that PAE may be offered for the treatment of LUTS/BPH. PAE should be performed by clinicians trained in this interventional radiology procedure. The panel was unable to find substantial evidence to recommend PAE over more widely available minimally invasive therapies for the routine treatment of LUTS, but there is evidence showing a short-term benefit of PAE compared to observation in a very select patient population. PAE is a technically demanding procedure, averaging fluoroscopy times of up to 50 minutes and procedure times up to 2 hours.

Guidelines:
American Urological Association - *Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia (BPH): AUA Guideline Amendment 2023*

- “PAE may be offered for the treatment of LUTS/BPH. PAE should be performed by clinicians trained in this interventional radiology procedure following a discussion of the potential risks and benefits. (Conditional Recommendation: Evidence level: Grade C)” (Sandhu et al, 2023)

European Association of Urology - *Non-Neurogenic Male Lower Urinary Tract Symptoms (LUTS) (2024)*

- “Offer prostatic artery embolization (PAE)* to men with moderate-tosevere LUTS who wish to consider minimally invasive treatment options and accept less optimal outcomes compared with transurethral resection of the prostate. [strength rating: weak]”
- “Perform PAE only in units where the work up and follow-up is performed by urologists working collaboratively with trained interventional radiologists for the identification of PAE suitable patients. [strength rating: strong]” (Cornu et al., 2024)

The Rezūm System (Boston Scientific)
Rezum is a minimally invasive, transurethral water vapor therapy treatment for lower urinary tract systems (LUTS) due to benign prostatic hyperplasia (BPH). Rezum utilizes convective radiofrequency (RF) water vapor energy to ablate hyperplastic tissue. Water vapor energy ablation to treat BPH tissue delivers RF generated thermal therapy using convection, the movement from a steam source of heated fluid carrying energy.

The Rezūm System consists of a radiofrequency power generator and a disposable delivery device. The rigid shaft of the delivery device incorporates a standard lens so that the procedure may be performed under cystoscopic visualization. The delivery device also contains a needle, which injects steam into diseased prostatic tissue. The steam immediately condenses to water thereby dispersing thermal energy and killing the surrounding cells. The dead cells are eventually absorbed, which reduces the volume of prostatic tissue and opens the urethra. The goal is to create contiguous, overlapping lesions approximately 1 cm apart along the urethra.

Guidelines:
American Urological Association - *Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia (BPH): AUA Guideline Amendment 2023*

- "Water Vapor Thermal Therapy (WVTT) should be considered as a treatment option for patients with LUTS/BPH provided prostate volume 30-80g. (Moderate Recommendation; Evidence Level: Grade C)"
- "WVTT may be offered as a treatment option to eligible patients who desire preservation of erectile and ejaculatory function. (Conditional Recommendation; Evidence Level: Grade C)" (Sandhu et al, 2023)

European Association of Urology - *Non-Neurogenic Male Lower Urinary Tract Symptoms (LUTS) (2024)*

- "Randomised controlled trials against a reference technique are needed to confirm the first promising clinical results and to evaluate mid- and long-term efficacy and safety of water vapor energy treatment." (Cornu et al., 2024)

Simple Prostatectomy – Open, Laparoscopic, or Robotic-Assisted
Open prostatectomy (OP) is the oldest surgical treatment for moderate-to-severe LUTS secondary to benign prostate obstruction (BPO) (EAU, 2024). Obstructive adenomas are enucleated using the index finger, approaching from within the bladder (Freyer procedure) or through the anterior prostatic capsule (Millin procedure). It is used for substantially enlarged glands (> 80-100 mL). The term minimal invasive simple prostatectomy (MISP) includes laparoscopic simple prostatectomy (LSP) and robot assisted simple prostatectomy (RASP). Both LSP and RASP are performed using different personalized techniques, based on the transcapsular (Millin) or transvesical (Freyer) approach.
A systematic review (SR) and meta-analyses of MISP showed that in 27 observational studies including 764 patients mean increase in Qmax was 14.3 mL/s, and the mean improvement in IPSS was 17.2. There were no differences in improvements in Qmax and IPSS. A meta-analysis comparing MISP vs. OP reported no significant differences with regard to functional and symptom parameters between the two techniques. A multicenter RCT with median follow-up of 26 months did not demonstrate any significantly different functional or perioperative results between LSP, RASP and HoLEP. A SR and meta-analysis of five non-randomized comparative trials comparing RASP with LSP demonstrated a shorter length of hospital stay after RASP as well as a higher post-operative Qmax. An RCT comparing HoLEP versus MISP for large volume (≥ 120 mL) prostate glands resulted in longer catheterization time in the LSP group than RASP and HoLEP groups (p=0.002). Furthermore, MISP resulted in longer hospitalisation, and lower rate of patients with new-onset of storage LUTS. (Cornu et al., 2024).

Guidelines:

American Urological Association - *Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia (BPH): AUA Guideline Amendment 2023*

- "Open, laparoscopic, or robotic assisted prostatectomy should be considered as treatment options by clinicians, depending on their expertise with these techniques, only in patients with large to very large prostates. (Moderate Recommendation; Evidence Level: Grade C) (Sandhu et al, 2023)

European Association of Urology - *Non-Neurogenic Male Lower Urinary Tract Symptoms (LUTS) (2024)*

- "Offer open prostatectomy in the absence of anatomical endoscopic enucleation of the prostate to treat moderate-to-severe LUTS in men with prostate size > 80 mL [strength rating: strong]"
- "Minimal invasive simple prostatectomy is feasible in men with prostate sizes > 80 mL needing surgical treatment; however, RCTs are needed." (Cornu et al., 2024)

Transurethral Incision of the Prostate (TUIP)

Transurethral incision of the prostate (TUIP) involves incising the bladder outlet without relevant tissue removal. Transurethral incision of the prostate is conventionally performed with Collins knife using electrocautery; however, alternative energy sources such as holmium laser may be used. The mainstay of this technique is in prostate sizes < 30 mL without a middle lobe. An RCT comparing conventional TUIP vs. TUIP using holmium laser in prostates ≤ 30 mL with a follow-up of twelve months, found both procedures to be equally effective in relieving BOO with similarly low re-operation rates. A meta-analysis of ten RCTs found similar LUTS improvements and lower but significant improvements in Qmax for TUIP. In this meta-analysis, an upper limit of prostate size was reported as an entry criterion for eight studies with five < 30 mL and three < 60 mL. A meta-analysis of six trials showed that re-operation was more common after TUIP (18.4%) than after M-TURP (7.2%) (Cornu et al., 2024).

Guidelines:

American Urological Association - *Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia (BPH): AUA Guideline Amendment 2023*

- "TUIP should be offered as an option for patients with prostates ≤30g for the surgical treatment of LUTS/BPH. (Moderate Recommendation; Evidence Level: Grade B)" (Sandhu et al, 2023)

European Association of Urology - *Non-Neurogenic Male Lower Urinary Tract Symptoms (LUTS) (2024)*

- "Offer transurethral incision of the prostate to surgically treat moderate-tosevere LUTS in men with prostate size < 30 mL, without a middle lobe. [strength rating: strong]" (Cornu et al., 2024)

Transurethral Resection of the Prostate (TURP)

Transurethral resection of prostate (TURP) has been the gold standard technique for surgical treatment of benign prostate hyperplasia (BPH) over the last several decades. Monopolar transurethral resection of prostate (M-TURP) is performed by passing high frequency current from a generator through an active electrode, allowing for electroresection of the prostate. Irrigation is used to provide a clear vision for the surgeon to continue resection of the vascular prostate. Bipolar transurethral resection of

prostate was introduced in the early 2000s as an alternative to M-TURP. Bipolar technology uses high frequency energy to create a vapor layer of plasma which contains energy-charged particles that induce tissue disintegration through molecular dissociation. As the active and return electrode are placed on the same axis of the resectoscope, high current densities are achieved locally and distant negative effects reduced. The reduction in lower resection temperature compared to conventional monopolar systems theoretically reduces thermal damage to surrounding tissue (Teo et al., 2017).

Guidelines:
American Urological Association – *Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia (BPH): AUA Guideline Amendment 2023*

- "TURP should be offered as a treatment option for patients with LUTS/BPH. (Moderate Recommendation; Evidence Level: Grade B)"
- "Clinicians may use a monopolar or bipolar approach to TURP as a treatment option, depending on their expertise with these techniques. (Expert Opinion)" (Sandhu et al, 2023)

European Association of Urology - *Non-Neurogenic Male Lower Urinary Tract Symptoms (LUTS) (2024)*

- "Offer bipolar- or monopolar-transurethral resection of the prostate to surgically treat moderate-to-severe LUTS in men with prostate size of 30- 80 mL [strength rating: strong]" (Cornu et al., 2024).

Transurethral Needle Ablation of the Prostate (TUNA)
Transurethral needle ablation of the prostate is an alternative surgical therapy for BPH that uses low energy radiofrequency delivered into the prostatic adenoma in the lateral lobes of the prostate, causing heat-induced coagulation necrosis. (Issa, 1996). TUNA is recognized as a "legacy technology" by the American Urological Association, which acknowledges that this procedure has largely been replaced by newer minimally invasive technologies.

Guidelines:
American Urological Association - Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia (BPH): AUA Guideline Amendment 2023

- "The panel recognizes several "legacy technologies" that have been historically used, and are currently FDA approved, but have very limited newly published data to be able to comment on their efficacy. The panel has observed that with newer minimally invasive technologies these "legacy technologies" are largely being displaced. The panel recognizes transurethral microwave thermotherapy of the prostate (TUMT) and transurethral needle ablation of the prostate (TUNA) as two of these legacy technologies, therefore guideline statement referencing these "legacy technologies" have been removed."

Transrectal Thermal Therapy/Transurethral Microwave Thermotherapy (TUMT)
Thermotherapy for treatment of BPH can be delivered via transrectal or transurethral routes. Transrectal thermal therapy has been largely replaced by Transurethral Vaporization of the Prostate (TUVP) transurethral microwave thermotherapy (TUMT). TUMT devices deliver relatively high microwave energy to the prostate, heating prostatic tissue to produce coagulation necrosis. With most devices the transurethral microwave

antenna is contained within a cooling catheter to prevent urethral thermal injury. (Hoffman et al., 2003). TUMT is recognized as a “legacy technology” by the American Urological Association, which acknowledges that this procedure has largely been replaced by newer minimally invasive technologies.

Transurethral Vaporization of the Prostate (TUVP)
Bipolar transurethral vaporization of the prostate (B-TUVP) utilizes a bipolar electrode and a high-frequency generator to create plasma field (thin layer of highly ionized particles) to vaporize prostatic tissue. Bipolar transurethral vaporisation of the prostate displays thinner (< 2 mm) coagulation zones, compared to monopolar TUVP (up to 10 mm), potentially resulting in fewer irritative side-effects and stress urinary incontinence (SUI). Bipolar-TUVP has been compared to TURP in thirteen RCTs, including a total of 1,244 men with a prostate size of < 80 mL. Early RCTs evaluated the PK B-TUVP system; however, during the last decade, only the “plasma” B-TUVP system with the “mushroom- or button-like” electrode (Olympus Medical) has been evaluated. Results have been pooled in three meta-analyses and a narrative synthesis has been produced in two SRs. Follow-up in most RCTs is twelve months with the longest being 36 months in a small RCT (n = 40) and eighteen months in a subsequent RCT (n = 340); evaluating PK and plasma B-TUVP, respectively. Results from meta-analyses concluded that no significant differences exist in short term efficacy (IPSS, QoL score, Qmax and PVR) between PK B-TUVP and TURP. This was confirmed in a separate SR of seven RCTs. Higher quality RCTs with longer follow-up are necessary to draw definite conclusions on mid and long-term outcomes (Cornu et al., 2024).

Guidelines:
American Urological Association - *Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia (BPH): AUA Guideline Amendment 2023*

- “Bipolar TUVP may be offered as an option to patients for the treatment of LUTS/BPH. (Conditional Recommendation; Evidence Level: Grade B)” (Sandhu et al, 2023)

European Association of Urology - *Non-Neurogenic Male Lower Urinary Tract Symptoms (LUTS) (2024)*

- “Offer bipolar transurethral vaporization of the prostate as an alternative to transurethral resection of the prostate to surgically treat moderate-to-severe LUTS in men with a prostate volume of 30-80 mL. [strength rating: weak]” (Cornu et al., 2024)

Transurethral Waterjet Ablation or Aquablation
Transurethral Waterjet Ablation or Aquablation is a minimally invasive procedure intended for the treatment of LUTS resulting from BPH using high pressure saline jet for targeted and heat-free resection and removal of prostate tissue. The procedure is performed with live transrectal ultrasound.

Guidelines: American Urological Association - Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia (BPH): AUA Guideline Amendment 2023

- “Robotic waterjet treatment (RWT) may be offered as a treatment option to patients with LUTS/BPH provided prostate volume 30-80g. (Conditional Recommendation; Evidence Level: Grade C)” (Sandhu et al, 2023).

European Association of Urology - Non-Neurogenic Male Lower Urinary Tract Symptoms (LUTS) (2024)

- "Offer Aquablation* to patients with moderate-to-severe LUTS and a prostate volume of 30-80 mL as an alternative to transurethral resection of the prostate. [strength rating: weak]"
- "Inform patients about the risk of bleeding and the lack of long-term follow-up data. [strength rating: strong]" (Cornu et al., 2024)

The UroLift System

Urolift is a minimally invasive, prostatic urethral lift (PUL) system that provides anterolateral mechanical traction of the lateral lobes of the prostate, opening the urethral lumen and reducing obstruction. Implants are delivered bilaterally to separate the encroaching lobes, beginning approximately 1.5 centimeters distal to the bladder neck. Cystoscopic inspection after each implant determines whether additional implants are required. Four to 5 implants are typically placed but this varies with the size and shape of the prostate. The device may avoid some of the morbidities and complications associated with other surgical approaches. The UroLift System is intended for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hypertrophy (BPH) in men ≥ 45 years of age with a prostate size up to 80 milliliters (mL) in size whose symptoms are refractory to medical therapy, and/or who are inappropriate candidates for more invasive procedures or who do not wish to undergo these procedures. The procedure is typically performed by an urologist in the office or other outpatient setting with the use of local anesthesia and oral sedation. In December 2019, the FDA approved an expansion of indication for the UroLift System to include lateral and median lobe hyperplasia and a prostate volume up to 100 cc.

The L.I.F.T. Study randomized 206 patients with BPH to implantation of the UroLift device versus a sham procedure and met its primary endpoint finding that patient treated with the device had a ≥ 25% reduction in the American Urological Association Symptom Index (AUASI) ($P<0.0001$) at 3 months compared with the sham controls, which was sustained at 1 year. Other endpoints that were improved at 3 months and at 1 year in the UroLift group compared with the controls included the Benign Prostatic Hyperplasia Impact Index (BPHII) ($P<0.001$ for both time points and maximum urinary flow rate (Qmax) ($P<0.0001$ for both time points). Changes in scores on the Male Sexual Health Questionnaire for Ejaculatory Dysfunction (MSHQ-EjD), MSHQ-bother, and International Index of Erectile Function (IIEF-5) were similar between the UroLift group and the controls at 3 months and at 1 year. These clinical benefits were sustained through 2 years as shown by follow-up of 106 patients available for analysis.

Guidelines:

American Urological Association - *Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia (BPH): AUA Guideline Amendment 2023*

- "Prostatic urethral lift (PUL) should be considered as a treatment option for patients with LUTS/BPH provided prostate volume 30-80g and verified absence of an obstructive middle lobe. (Moderate Recommendation; Evidence Level: Grade C)" (Sandhu et al, 2023)

European Association of Urology - *Non-Neurogenic Male Lower Urinary Tract Symptoms (LUTS) (2024)*

- Offer prostatic urethral lift (Urolift®) to men with LUTS interested in preserving ejaculatory function n, with prostates < 70 mL and no middle lobe." (Cornu et al., 2024).

Urethral Stricture

Drug Coated Balloon for Urethral Strictures

Urethral stricture disease is a narrowing of the urethral lumen caused by trauma, inflammation, infection, prior instrumentation, or malignancy, occurring predominantly in men, with >90% involving the anterior—especially bulbar—urethra. It impairs urinary function and quality of life, presenting with weak stream, incomplete emptying, dysuria, hematuria, urethral leaking, recurrent UTIs, frequency, pain, and possible sexual dysfunction. U.S. prevalence estimates are 200/100,000 men <65 and >600/100,000 men >65, contributing to 1.5 million visits and 5,000 hospitalizations annually (Abdeen et al., 2024; EAU, 2025). Risk factors include older age, sexually transmitted infections (especially gonorrhea), urethral trauma, prior catheterization or endoscopy, pelvic radiation, and prostate cancer treatment (Abdeen et al., 2024). Untreated strictures may progress to urinary retention, recurrent infection, voiding dysfunction, erectile dysfunction, or urethrocutaneous fistula (Abdeen et al., 2024).

Treatment options depend on stricture characteristics. Endoscopic dilation and direct vision internal urethrotomy (DVIU) are minimally invasive but have high recurrence rates, particularly with repeated use, and may worsen scarring or compromise future urethroplasty (Abdeen et al., 2024; Estaphanous et al., 2024; UCF, 2024; EAU, 2025; McGeorge et al., 2019). Urethroplasty (anastomotic or substitution repair, perineal urethrostomy) remains the gold standard, especially for recurrent disease, but is more invasive and may cause sexual dysfunction, neuropathy, or postoperative pain (Elliott et al., 2022; Abdeen et al., 2024). Per the American Urological Association (AUA) (2023), stricture length and location should guide management; short (<2 cm) bulbar strictures may be managed endoscopically after urethral rest, while urethroplasty is recommended for primary or recurrent anterior/posterior strictures. In female patients, urethroplasty using oral mucosa grafts or vaginal flaps is preferred.

Optilume® urethral drugcoated balloon (DCB) delivers mechanical dilation with local paclitaxel therapy to reduce hyperproliferation and recurrence. Designed for strictures ≤3 cm, Optilume is delivered transurethrally, inflated to restore patency, and provides antiproliferative drug delivery while minimizing tissue trauma (FDA, 2021; Laborie, 2025).

Clinical evidence for the Optilume drugcoated balloon (DCB) is supported by multiple prospective and randomized trials.

ROBUST I was a prospective clinical trial evaluating the Optilume drugcoated balloon (DCB) for the treatment of recurrent anterior/bulbar urethral strictures in men. It represents the first pivotal study of a paclitaxelcoated balloon designed for urethral strictures. Virasoro et al. (2022) noted that the 3year findings of the ROBUST I trial demonstrate that the Optilume® drugcoated balloon (DCB) provided sustained clinical benefit for men with recurrent bulbar urethral strictures ≤2 cm who previously underwent 1–4 endoscopic treatments. Among 43 evaluable patients, functional success (≥50% IPSS improvement without retreatment) was achieved in 67%, and freedom from reintervention occurred in 77%. Symptom severity (mean International Prostate

Symptom Score (IPSS)) improved substantially from 25.2 to 5.5, with parallel improvements in quality of life, urinary flow rate, and postvoid residual volume. Erectile function remained unchanged. Reported devicerelated adverse events were mild or moderate, selflimited, and no serious treatmentrelated events occurred. These results demonstrate that Optilume provides durable, minimally invasive symptom relief in a population at high risk for recurrence.

DeLong et al. (2025) reported the 5year results of the ROBUST I trial showing that the Optilume drugcoated balloon (DCB) provided durable, longterm benefit for men with recurrent bulbar urethral strictures ≤2 cm. Among 53 treated patients (43 evaluable), functional success (≥50% IPSS improvement without retreatment) was achieved in 58% at 5 years. Significant improvements were sustained in IPSS (25.2 → 7.2), maximum flow rate (5.0 → 19.9 mL/s), and postvoid residual (141.4 → 59.5 mL). Freedom from repeat intervention remained high at 71.7%, and erectile function was unchanged. No serious treatmentrelated adverse events occurred. These results confirm that Optilume offers a safe, effective, and durable minimally invasive option for appropriately selected men seeking alternatives to urethroplasty.

The **ROBUST II** study was a smaller, earlierphase clinical study evaluating the Optilume® drugcoated balloon (DCB). Sixteen participants were treated and followed for 1 year. At 6 months, anatomic success was achieved in 73%. By 1 year, the average IPSS improved from 18.4 to 6.0 and Qmax increased from 6.9 to 20.8 mL/s (both $p < 0.001$). Erectile function remained unchanged, and no treatmentrelated serious complications occurred; four patients required additional treatment within 1 year. These findings demonstrate that Optilume provided meaningful symptomatic improvement and favorable safety in shortterm followup (DeLong et al., 2022).

The **ROBUST III** randomized, singleblind trial evaluated the Optilume® drugcoated balloon (DCB) versus standard endoscopic management (dilation/DVIU) in adult men with recurrent anterior urethral strictures ≤3 cm, ≤12 Fr in diameter, ≥2 prior endoscopic treatments, IPSS ≥11, and Qmax <15 mL/s (n=127). Optilume demonstrated significantly better outcomes, with 6month anatomic success of 75% vs 27% and 1year freedom from repeat intervention of 83% vs 22%. At 1 year, Optilume also showed greater improvement in urinary symptoms (IPSS 9 vs 20) and flow rate (Qmax 16 vs 8 mL/s) compared with dilation/DVIU. Adverse events were generally mild and similar between groups, though hematuria and dysuria occurred more frequently with Optilume (11% vs 2%). Overall, the study concluded that Optilume is safe and more effective than standard endoscopic therapy for recurrent anterior urethral strictures <3 cm and offers a minimally invasive alternative for patients seeking to avoid or delay urethroplasty (Elliott et al., 2022).

VanDyke et al (2024) reported on the 2year results of the ROBUST III randomized trial indicating that the Optilume drugcoated balloon (DCB) provides sustained clinical benefit for men with recurrent anterior urethral strictures ≤3 cm, ≤12 Fr, IPSS ≥11, and Qmax <15 mL/s. Among 127 enrolled participants, those treated with Optilume demonstrated durable improvements in IPSS, Qmax, and postvoid residual, with freedom from repeat intervention at 2 years of 77.8%, significantly higher than the standardofcare control arm at 1 year (23.6%). Treatmentrelated adverse events—such as hematuria, dysuria, and

UTI—were infrequent and selflimited, and no serious device or procedurerelated events occurred. These findings support Optilume as a safe and effective minimally invasive alternative for men with short recurrent anterior urethral strictures who wish to avoid or delay urethroplasty.

The 3year results of the ROBUST III trial (Srikanth et al., 2025) show that the Optilume® drugcoated balloon (DCB) provides durable symptom improvement and reduced reintervention rates for recurrent anterior urethral strictures ≤3 cm. Freedom from reintervention remained 71% at 3 years, similar to 2year outcomes and roughly three times higher than the control group at 1 year. Improvements in IPSS, Qmax, and PVR were sustained across all subgroups, including those with ≥5 prior dilations or longer strictures. Crossover patients mirrored the outcomes of the primary DCB cohort. Adverse events were rare and selflimited, mainly hematuria, dysuria, and UTI. Optilume continues to demonstrate a durable, safe, minimally invasive alternative to repeated endoscopic treatment.

Across multiple prospective and randomized trials, the Optilume drugcoated balloon consistently demonstrates durable symptom relief, improved urinary flow, and significantly reduced need for repeat intervention, with a favorable safety profile. Evidence supports Optilume as a safe and effective minimally invasive alternative for appropriately selected adult men with recurrent anterior or bulbar urethral strictures ≤3 cm, particularly those seeking to avoid or delay urethroplasty.

Guidelines:

American Urological Association **-** *Urethral Stricture Disease Guideline Amendment 2023*

- 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-*EAU Guidelines on Urethral Strictures 2025*

- 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- *Optilume for Treating Recurrent Bulbar Urethral Strictures 2022*

- 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.
- Optilume is intended as a second-line treatment for urethral strictures in people who have had at least 1 previous endoscopic procedure that has failed. The technology is used by trained consultants in urology, urology trainees and urology nurse specialists. It can be done using local anaesthesia as a day case or in an outpatient setting.

IV. GUIDELINES / POSITION STATEMENTS

Medical/Professional Society	Guideline
American Urological Association	Benign Prostatic Hyperplasia (BPH) Guideline - American Urological Association Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: AUA GUIDELINE PART II—Surgical Evaluation and Treatment | Journal of Urology Surgical Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: AUA Guideline | Journal of Urology Urethral Stricture - AUA Guideline - American Urological Association
European Association of Urology	EAU Guidelines on the Management of Non-neurogenic Male LUTS - INTRODUCTION EAU Guidelines on Urethral Strictures - INTRODUCTION
National Institute Diabetes and Digestive and Kidney Disease (NIDDK)	Enlarged Prostate (Benign Prostatic Hyperplasia) - NIDDK
Society of Interventional Radiology	Society of Interventional Radiology Position Statement: Prostate Artery Embolization for Treatment of Benign Disease of the Prostate - Journal of Vascular and Interventional Radiology

National Institute for Health and Care Excellence (NICE)	Optilume for treating recurrent bulbar urethral strictures

V. REGULATORY (US FOOD AND DRUG ADMINISTRATION)

See U.S. Food & Drug Administration (FDA) Medical Device Databases for the most current information.

Device	Premarket Approval, 513(f)(2)(De Novo), or 510(k) Number	Notice date
AquaBeam Robotic System (Aquablation) manufactured by PROCEPT BioRobotics	DEN170024	12/2017
The Spanner Temporary Prostatic Stent	P060010/S013	10/7/2022
UroLume Endourethral Prosthesis)	P920023	0411/1997
EMBOSPHERE MICROSPHERES	DEN160040	06/2017
Transurethral Microwave Therapy Device (TUMT)	P030006	02/19/2004
Transurethral Needle Ablation of the Prostate (TUNA)	K965199 K960918 K951245	04/30/1997
Rezūm System	K150786	8/24/2015
UroLift® System (Neotract, INC)	K173087	12/28/2017
GreenLight laser™ (GLL) (American Medical Systems)	K092735	11/09/2009
GreenLight HPS SURGICAL LASER SYSTEM & Accessories	K062719	12/01/2006
High Intensity Ultrasound System For Prostate Tissue Ablation	K251910	11/19/2025
FOCAL ONE	K251910 K172721	11/19/2025 06/07/2018
Exablate Model 2100V1, Exablate Prostate System, Exablate MRgFUS, Exablate 2100V1 Type 3.0	K231378 K212150	10/30/2023 11/23/2021
TULSA-PRO System	K240296 K230692 K211858	05/09/2024 09/20/2023 09/06/2022

Ablatherm Fusion	K172285	10/03/2017
Optilume® High Pressure Urological Balloon Dilation Catheter (Urotronic, Inc.) Optilume Basic Urological Balloon Dilation Catheter (Urotronic, Inc.)	K250910 K191061	05/22/2025 01/02/2020
Optilume Urethral Drug Coated Balloon	P210020	12/03/2021

VI. CODING

See also Priority Health Billing Policy No. 173 Benign Prostatic Hyperplasia Treatments

BPH
ICD-10 Codes that may support medical necessity

N40.1 Benign prostatic hyperplasia with lower urinary tract symptoms

CPT/HCPCS Codes

52441 Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant

52442 Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; each additional permanent adjustable transprostatic implant (List separately in addition to code for primary procedure)

52450 Transurethral incision of prostate (TUIP) (TUVP)

52500 Transurethral resection of bladder neck (separate procedure)

52597 Transurethral robotic-assisted waterjet resection of prostate, including intraoperative planning, ultrasound guidance, control of postoperative bleeding, complete, including vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy, when performed

52601 Transurethral electrosurgical resection of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included)

52630 Transurethral resection; residual or regrowth of obstructive prostate tissue including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included)

52648 Laser vaporization of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, internal urethrotomy and transurethral resection of prostate are included if performed) (PVP)

52649	Laser enucleation of the prostate with morcellation, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, internal urethrotomy and transurethral resection of prostate are included if performed) (HoLEP)
53854	Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy (Rezum)

Outpatient Facility Codes:

C2596	Probe, image guided, robotic, waterjet ablation
C9739	Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants
C9740	Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants
L8699	Prosthetic implant, not otherwise specified

Not Covered:

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
53850	Transurethral destruction of prostate tissue; by microwave thermotherapy
53852	Transurethral destruction of prostate tissue; by radiofrequency thermotherapy
52282	Cystourethroscopy, with insertion of permanent urethral stent
0582T	Transurethral ablation of malignant prostate tissue by high-energy water vapor thermotherapy, including intraoperative imaging and needle guidance
0714T	Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance; prostate volume less than 50 mL
0867T	Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance; prostate volume greater or equal to 50 mL
0941T	Cystourethroscopy, flexible; with insertion and expansion of prostatic urethral scaffold using integrated cystoscopic visualization
0942T	Cystourethroscopy, flexible; with removal and replacement of prostatic urethral scaffold
0943T	Cystourethroscopy, flexible; with removal of prostatic urethral scaffold
51721	Insertion of transurethral ablation transducer for delivery of thermal ultrasound for prostate tissue ablation, including suprapubic tube placement during the same session and placement of an endorectal cooling device, when performed
53865	Cystourethroscopy with insertion of temporary device for ischemic remodeling (i.e., pressure necrosis) of bladder neck and prostate (Covered for Medicaid and Medicare)
53866	Catheterization with removal of temporary device for ischemic remodeling (i.e., pressure necrosis) of bladder neck and prostate (Covered for Medicaid and Medicare)
55881	Ablation of prostate tissue, transurethral, using thermal ultrasound, including magnetic resonance imaging guidance for, and monitoring of, tissue ablation (Covered for Medicaid and Medicare)

55882	Ablation of prostate tissue, transurethral, using thermal ultrasound, including magnetic resonance imaging guidance for, and monitoring of, tissue ablation; with insertion of transurethral ultrasound transducer for delivery of thermal ultrasound, including suprapubic tube placement and placement of an endorectal cooling device, when performed (Covered for Medicaid and Medicare)

Prostatic Artery Embolization
ICD-10 Codes that may support medical necessity

N40.1	Benign prostatic hyperplasia with lower urinary tract symptoms
N40.3	Nodular prostate with lower urinary tract symptoms

CPT/HCPCS Codes

37243	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural road mapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction
72191	Computed tomographic angiography, pelvis, with contrast material(s), including non-contrast images, if performed, and image postprocessing

Urethral Stricture

Drug Coated Balloon for Urethral Stricture (i.e., Optilume)
ICD-10 Codes that may support medical necessity

N35.01	Post-traumatic urethral stricture, male
N35.11	Postinfective urethral stricture, not elsewhere classified, male
N35.81	Other urethral stricture, male
N35.91	Urethral stricture, unspecified, male
N99.11	Postprocedural urethral stricture, male

CPT/HCPCS Codes

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

VII. MEDICAL NECESSITY REVIEW

Prior authorization for certain drugs, devices, services and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service or procedure is medically necessary. For more information, refer to the Priority Health Provider Manual.

To access Evicore guidelines: Log into Priority Health Prism → Authorizations → Authorization Criteria Lookup.

To access InterQual guidelines: Log into Priority Health Prism → Authorizations → Authorization Criteria Lookup

Individual case review may allow coverage for care or treatment that is investigational yet promising for the conditions described. Requests for individual consideration require

prior plan approval. All determinations of coverage for experimental, investigational, or unproven treatment will be made by a Priority Health medical director or clinical pharmacist. The exclusion of coverage for experimental, investigational, or unproven treatment may be reviewed for exception if the condition is either a terminal illness, or a chronic, life threatening, severely disabling disease that is causing serious clinical deterioration.

VIII. APPLICATION TO PRODUCTS

Coverage is subject to the member's specific benefits. Group-specific policy will supersede this policy when applicable.

- **HMO/EPO**: This policy applies to insured HMO/EPO plans.
- **POS**: This policy applies to insured POS plans.
- **PPO**: This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.
- **ASO**: For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.
- **INDIVIDUAL**: For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.
- **MEDICARE**: Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.
- **MEDICAID/HEALTHY MICHIGAN PLAN**: For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.

IX. REFERENCES

General

1. EAU Guidelines. Edn. presented at the EAU Annual Congress Paris April 2024. ISBN 978-94-92671-23-3
2. Sandhu, J. S., Bixler, B. R., Dahm, P., Goueli, R., Kirkby, E., Stoffel, J. T., & Wilt, T. J. (2024). Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia (BPH): AUA Guideline Amendment 2023. The Journal of urology, 211(1), 11–19. https://doi.org/10.1097/JU.0000000000003698
3. Foster HE et al. Surgical Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: AUA Guideline Amendment 2019. The Journal of Urology. 2019; 202: 592-598
4. Lerner LB, McVary KT, Barry MJ, Bixler BR, Dahm P, Das AK, Gandhi MC, Kaplan SA, Kohler TS, Martin L, Parsons JK, Roehrborn CG, Stoffel JT, Welliver C, Wilt TJ. Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: AUA GUIDELINE PART II Surgical Evaluation and Treatment. J Urol. 2021 Oct;206(4):818-826.

5. National Institute Diabetes and Digestive and Kidney Disease (NIDDK). Prostate Enlargement (Bening Prostatic Hyperplasia). Available at https://www.niddk.nih.gov/health-information/urologic-diseases/prostate-problems/prostate-enlargement-benign-prostatic-hyperplasia#benign (Accessed August 22, 2025).
6. Sandhu JS et al. Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia (BPH): AUA Guideline Amendment 2023. J Urol. 2024 Jan;211(1):11-19.
7. Society of Interventional Radiology Position Statement, J Vasc Interv Radiol 2014; 25:1349–1351
8. UpToDate. Surgical treatment of benign prostatic hyperplasia (Authors: Cunningham GR & MD, Kadmon D). Publication Date: June 24, 2019

Prostate Artery Embolization
9. Abt D, Hechelhammer L, Mullhaupt G, et al. Comparison of prostatic artery embolisation (PAE) versus transurethral resection of the prostate (TURP) for benign prostatic hyperplasia: randomised, open label, non-inferiority trial. BMJ. 2018a;361:k2338.
10. Abt D, Müllhaupt G, Hechelhammer L, et al. Prostatic artery embolisation versus transurethral resection of the prostate for benign prostatic hyperplasia: 2-yr outcomes of a randomised, open-label, single-centre trial. Eur Urol. 2021;80(1):34-42. doi:10.1016/j.eururo.2021.02.008
11. Abt D, Müllhaupt G, Mordasini L, et al. Outcome prediction of prostatic artery embolization: post hoc analysis of a randomized, open-label, noninferiority trial. BJU Int. 2019;124(1):134-144. doi:10.1111/bju.14632
12. Bhatia, A., Porto, J. G., Maini, A., Langade, D., Herrmann, T. R. W., Shah, H. N., & Bhatia, S. (2023). One-year outcomes after prostate artery embolization versus laser enucleation: A network meta-analysis. BJUI compass, 5(2), 189–206. https://doi.org/10.1002/bco2.302
13. Pisco JM, Bilhim T, Costa NV, et al. Randomised clinical trial of prostatic artery embolisation versus a sham procedure for benign prostatic hyperplasia. Eur Urol. 2020;77(3):354-362. doi:10.1016/j.eururo.2019.11.010
14. McWilliams JP, Bilhim TA, Carnevale FC, et al. Society of Interventional Radiology Multisociety Consensus Position Statement on Prostatic Artery Embolization for Treatment of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: From the Society of Interventional Radiology, the Cardiovascular and Interventional Radiological Society of Europe, Société Française de Radiologie, and the British Society of Interventional Radiology: Endorsed by the Asia Pacific Society of Cardiovascular and Interventional Radiology, Canadian Association for Interventional Radiology, Chinese College of Interventionalists, Interventional Radiology Society of Australasia, Japanese Society of Interventional Radiology, and Korean Society of Interventional Radiology. J Vasc Interv Radiol. 2019 May;30(5):627-637.e1. doi: 10.1016/j.jvir.2019.02.013. Epub 2019 Mar 27. PMID: 30926185.
15. Mirakhur A, McWilliams JP. Prostate Artery Embolization for Benign Prostatic Hyperplasia: Current Status. Can Assoc Radiol J. 2017 Feb; 68(1):84-89.
16. Kuang M, Vu A, Athreya. A Systematic Review of Prostatic Artery Embolization in the Treatment of Symptomatic Benign Prostatic Hyperplasia. S.Cardiovasc Intervent Radiol. 2017 May; 40(5):655-663.

17. Malling B, Røder MA, Brasso K, Forman J, Taudorf M, Lönn L. Prostate artery embolisation for benign prostatic hyperplasia: a systematic review and meta-analysis. Eur Radiol. 2019;29(1):287-298.
18. Ray AF, Powell J, Speakman MJ, et al. Efficacy and safety of prostate artery embolization for benign prostatic hyperplasia: an observational study and propensity-matched comparison with transurethral resection of the prostate (the UK-ROPE study). BJU Int. 2018;122(2):270-282
19. Uflacker A, Haskal ZJ, Bilhim T, Patrie J, Huber T, Pisco JM. MetaAnalysis of Prostatic Artery Embolization for Benign Prostatic Hyperplasia. J Vasc Interv Radiol. 2016 Nov; 27(11):1686-1697.
20. Zumstein V, Betschart P, Vetterlein MW, Kluth LA, Hechelhammer L, Mordasini L, Engeler DS, Kessler TM, Schmid HP, Abt D. Prostatic Artery Embolization versus Standard Surgical Treatment for Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia: A Systematic Review and Meta-analysis. Eur Urol Focus. 2019 Nov;5(6):1091-1100. doi: 10.1016/j.euf.2018.09.005.

Holmium Laser Enucleation (HoLEP), Thulium Laser Enucleation (ThuLEP)
21. Porreca, A., Colicchia, M., Tafuri, A., D'Agostino, D., Busetto, G. M., Crestani, A., Odorizzi, K., Amigoni, N., Rizzetto, R., Gozzo, A., Gallina, S., Bianchi, L., Ferro, M., Falabella, R., Romagnoli, D., Antonelli, A., Corsi, P., & Schiavina, R. (2022). Perioperative Outcomes of Holmium Laser Enucleation of the Prostate: A Systematic Review. Urologia internationalis, 106(10), 979–991. https://doi.org/10.1159/000518560
22. Hartung FO et al, Holmium Versus Thulium Laser Enucleation of the Prostate: A Systematic Review and Meta-analysis of Randomized Controlled Trials. Eur Urol Focus. 2022 Mar;8(2):545-554.

Temporary Implanted Prostatic Devices
23. Cambio AJ, Roach RM, Arnold P, Cambio J, Gluck CD, Heron SP. Extended Use of The Spanner® Temporary Prostatic Stent in Catheter-Dependent Men with Comorbidities. Adv Urol. 2022 Feb 3;2022:7367851
24. Kernen KM, Omar S, Goodnight B, Skodny P, Bruce S, Yu TM. Temporarily implanted nitinol device versus prostatic urethral lift for minimally invasive surgical treatment of benign prostatic hyperplasia with lower urinary tract symptoms: a matching-adjusted indirect comparison. Can J Urol. 2023 Oct;30(5):11676-11685.
25. McKenzie P, Badlani G. Critical appraisal of the Spanner™ prostatic stent in the treatment of prostatic obstruction. Med Devices (Auckl). 2011;4:27- 33. doi: 10.2147/MDER.S7107. Epub 2011 Feb 9. PMID: 22915927

Transurethral Resection of the Prostate
26. Carnevale FC, Iscaife A, Yoshinaga EM, Moreira AM, Antunes AA, Srougi M. Transurethral resection of the prostate (TURP) versus original and PErFecTED prostate artery embolization (PAE) due to benign prostatic hyperplasia (BPH): preliminary results of a single center, prospective, Uuodynamic-controlled analysis. Cardiovasc Intervent Radiol. 2016;39(1):44-52.
27. Teo JS, Lee YM, Ho HSS. An update on transurethral surgery for benign prostatic obstruction. Asian J Urol. 2017 Jul;4(3):195-198.
28. Jiang YL, Qian LJ. Transurethral resection of the prostate versus prostatic artery embolization in the treatment of benign prostatic hyperplasia: a meta-analysis. BMC Urol. 2019 Jan 28;19(1):11.

29. Insausti I, Sáez de Ocáriz A, Galbete A, et al. Randomized comparison of prostatic artery embolization versus transurethral resection of the prostate for treatment of benign prostatic hyperplasia. J Vasc Interv Radiol. 2020;31(6):882-890.

Photoselective Vaporization of the Prostate (PVP)
30. Castellani D, Pirola GM, Rubilotta E, Gubbiotti M, Scarcella S, Maggi M, Gauhar V, Teoh JY, Galosi AB. GreenLight Laser™ Photovaporization versus Transurethral Resection of the Prostate: A Systematic Review and Meta-Analysis. Res Rep Urol. 2021 May 20;13:263-271.
31. Darson et al. Procedural techniques and multicenter postmarket experience using minimally invasive convective radiofrequency thermal therapy with Rezūm system for treatment of lower urinary tract symptoms due to benign prostatic hyperplasia. Res Rep Urol. 2017; 9: 159–168.
32. Dixon et al. Transurethral convective water vapor as a treatment for lower urinary tract symptomatology due to benign prostatic hyperplasia using the Rezūm® system: evaluation of acute ablative capabilities in the human prostate. Res Rep Urol. 2015; 7: 13–18.
33. McVary et al. Rezūm Water Vapor Thermal Therapy for Lower Urinary Tract Symptoms Associated With Benign Prostatic Hyperplasia: 4-Year Results From Randomized Controlled Study. Urology. 2019
34. U.S. Food and Drug Administration (FDA). Rezum System (K150786). 510(k) premarket notification @ https://www.accessdata.fda.gov/cdrh_docs/pdf15/K150786.pdf

Prostatic Urethral Lift
35. Roehrborn CG, Barkin J, Gange SN, Shore ND, Giddens JL, Bolton DM, Cowan BE, Cantwell AL, McVary KT, Te AE, Gholami SS, Moseley WG, Chin PT, Dowling WT, Freedman SJ, Incze PF, Coffield KS, Herron S, Rashid P, Rukstalis DB. Five year results of the prospective randomized controlled prostatic urethral L.I.F.T. study. Can J Urol. 2017 Jun;24(3):8802-8813. PMID: 28646935.
36. Roehrborn, C. G., Gange, S. N., et.al. Durability of the prostatic urethral lift: 2-year results of the L.I.F.T. Study. Urology Practice Journal, 16 September 2014.
37. Rukstalis D et al. Prostatic Urethral Lift (PUL) for obstructive median lobes: 12 month results of the MedLift Study. Prostate Cancer and Prostatic Diseases (2019) 22:411–419.
38. Jung JH, Reddy B, McCutcheon KA, Borofsky M, Narayan V, Kim MH, Dahm P. Prostatic urethral lift for the treatment of lower urinary tract symptoms in men with benign prostatic hyperplasia. Cochrane Database Syst Rev. 2019 May 25;5(5):CD012832. PMID: 31128077; PMCID: PMC6535104.
39. Neotract, Inc. Urolift System UL 400, Instructions for Use. Available at https://www.urolift.com/physicians/procedures-devices/ifu (Retrieved July 19, 2024).
40. U.S. Food and Drug Administration (FDA). UroLift System (UL400 And UL500).510(k) Premarket Notification @ https://www.accessdata.fda.gov/cdrh_docs/pdf17/K173087.pdf

Transurethral Waterjet Ablation (Aquablation)
41. Desai M, Bidair M, Bhojani N et al. Aquablation for benign prostatic hyperplasia in large prostate (80-150 cc): 2-year results Can J Urol. 2020; 27(2): 10147-10153.
42. Desai M, Bidair M, Bhojani N, Trainer A, Arther A, Kramolowsky E, et al. WATER II (80–150 mL) procedural outcomes. BJU Int 2019;123(1):106-112.

43. Gilling P, Barber N, Bidair M, et al. Two-year outcomes after aquablation compared to TURP: Efficacy and ejaculatory improvements sustained. Adv Ther. 2019;(6):1326-1336.
44. Gilling P, Barber N, Bidair M, et al. WATER: A double-blind, randomized, controlled trial of Aquablation vs transurethral resection of the prostate in benign prostatic hyperplasia. J Urol. 2018;199(5):1252- 1261.
45. Hwang EC, Jung JH, Borofsky M, et al. Aquablation of the prostate for the treatment of lower urinary tract symptoms in men with benign prostatic hyperplasia. Cochrane Database Syst Rev. 2019;2:CD013143.
46. McVary KT, Gange SN, Gittelman MC, et al. Minimally invasive prostate convective water vapor energy ablation: a multicenter, randomized, controlled study for the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia. J Urol. 2016; 195(5):1529- 1538.

Transrectal Thermal Therapy, Transurethral Microwave Thermotherapy (TUMT)
47. Hoffman RM, et al. Transurethral microwave thermotherapy vs transurethral resection for treating benign prostatic hyperplasia: a systematic review. BJU Int. 2004 Nov;94(7):1031-6.
48. European Association of Urology (EAU) Guidelines. Edn. presented at the EAU Annual Congress Paris April 2024. ISBN 978-94-92671-23-3

Transurethral Needle Ablation of the Prostate (TUNA)
49. Issa MM. Transurethral needle ablation of the prostate: report of initial United States clinical trial. J Urol. 1996 Aug;156(2 Pt 1):413-9. PMID: 8683692.

Optilume for BPH
50. Kaplan SA, et al. The PINNACLE Study: A Double-blind, Randomized, Sham-controlled Study Evaluating the Optilume BPH Catheter System for the Treatment of Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia. J Urol. 2023 Sep;210(3):500-509.
51. Kaplan SA, Moss JL, Freedman SJ. Two-year long-term follow-up of treatment with the Optilume BPH catheter system in a randomized controlled trial for benign prostatic hyperplasia (The PINNACLE Study). *Prostate Cancer Prostatic Dis*. 2024;27(3):531-536. doi:10.1038/s41391-024-00833-z
52. Kaplan SA, Pichardo M, Rijo E, Espino G, Lay RR, Estrella R. Long-term outcomes after treatment with Optilume BPH Four-year results from the EVEREST study. *Can Urol Assoc J*. 2024;18(11):E319-E325. doi:10.5489/cuaj.8737
53. Kaur, Parminder, and Sharanjot Saini. “The Optilume BPH Catheter System for the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia.” *Translational andrology and urology* vol. 13,6 (2024): 1071-1073. doi:10.21037/tau-23-673

UroLume
54. Yip KH, Lee F, Lam PC, Ho KK. Urolume prostatic stents for urinary retention due to benign prostatic hyperplasia in patients with high medical risks. Hong Kong Med J. 1997 Jun;3(2):136-140.
55. Armitage JN, Cathcart PJ, Rashidian A, De Nigris E, Emberton M, van der Meulen JH. Epithelializing stent for benign prostatic hyperplasia: a systematic review of the literature. J Urol. 2007 May;177(5):1619-24.

56. Cerrato, C., Antoniou, V., & Somani, B. K. (2025). Prostatic stents: a systematic review and analysis of functional outcomes and complication rate. Prostate cancer and prostatic diseases, 28(2), 318–327. https://doi.org/10.1038/s41391-024-00915-y

Urethral Stricture

57. Abdeen BM, Leslie SW, Badreldin AM. Urethral Strictures. 2024 Oct 29. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan–. PMID: 33231967.
58. American Urological Association. (2023). *Urethral stricture guideline*. https://www.auanet.org/guidelines-and-quality/guidelines/urethral-stricture-guideline
59. DeLong, J. M., Ehlert, M. J., Erickson, B. A., Robertson, K. J., Virasoro, R., & Elliott, S. P. (2022). One-Year Outcomes of the ROBUST II Study Evaluating the Use of a Drug-Coated Balloon for Treatment of Urethral Stricture. *Société Internationale d'Urologie Journal*, *3*(1), 21-27. https://doi.org/10.48083/MLXK5817
60. DeLong J, Virasoro R, Pichardo M, Estrella R, Rodríguez Lay R, Espino G, Elliott S. Long-Term Outcomes of Recurrent Bulbar Urethral Stricture Treatment With the Optilume Drug-Coated Balloon: Five-Year Results From the ROBUST I Study. J Urol. 2025 Jan;213(1):90-98. doi: 10.1097/JU.0000000000004229. Epub 2024 Aug 30. PMID: 39213367; PMCID: PMC12708045.
61. Elliott, Sean P et al. "One-Year Results for the ROBUST III Randomized Controlled Trial Evaluating the Optilume® Drug-Coated Balloon for Anterior Urethral Strictures." *The Journal of urology* vol. 207,4 (2022): 866-875. doi:10.1097/JU.0000000000002346
62. European Association of Urology. (2025). *Disease management in males*. In *EAU guidelines on urethral strictures*. https://uroweb.org/guidelines/urethral-strictures/chapter/disease-management-in-males
63. Food and Drug Administration. (2021). *Premarket approval (PMA): Optilume urethral drug-coated balloon (P210020)*. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P210020
64. Laborie Medical Technologies Corp. Optilume® urethral drug coated balloon for the treatment of anterior urethral stricture. 2026. Accessed January 09, 2026. https://www.laborie.com/product/optilume-drug-coated-balloon-for-urethral-stricture-treatment/
65. McGeorge S, Chung A, Desai DJ. Trends in urethral stricture management over two decades. BJU Int. 2019 Nov;124 Suppl 1:37-41. doi: 10.1111/bju.14875. Epub 2019 Oct 22. PMID: 31638318.
66. National Institute for Health and Care Excellence. (2022). *Optilume for treating recurrent bulbar urethral strictures* (Medical technologies guidance MTG73). https://www.nice.org.uk/guidance/mtg73
67. Srikanth P, DeLong J, Virasoro R, Elliott SP. A Drug-Coated Balloon Treatment for Urethral Stricture Disease: Three-Year Results from the ROBUST III Study. J Endourol. 2025 Sep;39(9):968-974. doi: 10.1089/end.2024.0718. Epub 2025 Jun 2. PMID: 40300835.
68. Urology Care Foundation (UCF). What is urethral stricture disease? October 2024. Accessed January 01, 2026. https://www.urologyhealth.org/urology-a-z/u/urethral-stricture-disease

69. VanDyke, Maia E et al. “Optilume drug-coated balloon for anterior urethral stricture: 2-year results of the ROBUST III trial.” *BJUI compass* vol. 5,3 366-373. 18 Dec. 2023, doi:10.1002/bco2.312
70. Virasoro, Ramón et al. “A Drug-Coated Balloon Treatment for Urethral Stricture Disease: Three-Year Results from the ROBUST I Study.” *Research and reports in urology* vol. 14 177-183. 6 May. 2022, doi:10.2147/RRU.S359872
71. Wessells H, Morey A, Vanni A, Rahimi L, Souter L. Urethral stricture disease guideline amendment (2023). J Urol. 2023;210(1):64-71.

Past review dates:08/2024, 08/2025, 02/2026