

07.01.97 Miscellaneous Minimally-Invasive Treatments for Benign Prostatic Hyperplasia

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Related Policies:

- [02.01.53 High Intensity Focused Ultrasound \(HIFU\)](#)
- [07.01.94 Prostatic Urethral Lift](#)
- [07.01.95 Temporarily Implanted Nitinol Device \(iTind\) for Benign Prostatic Hyperplasia](#)
- [07.01.96 Transurethral Water Vapor Thermal Therapy \(Rezum\) and Transurethral Waterjet Ablation \(Aquablation\) for Benign Prostatic Hypertrophy](#)

Summary

Description

Minimally invasive treatments are options to relieve symptoms of benign prostatic hyperplasia (BPH) while minimizing hospitalizations and complications of other treatments.

Summary of Evidence

For individuals who have benign prostatic hypertrophy (BPH) and lower urinary tract symptoms (LUTS) who receive minimally invasive treatments including holmium laser ablation of the prostate [HoLAP], holmium laser enucleation of the prostate [HoLEP], holmium laser resection of the prostate [(HoLRP], photoselective vaporization (PVP), transurethral electro vaporization of the prostate (TUVF), transurethral microwave thermotherapy (TUMT), transurethral incision of the prostate (TUIP) and visually guided laser ablation of the prostate (VLAP), the evidence includes comparative trials. The outcomes of interest are symptoms, functional outcomes, quality of life (QOL), and treatment-related morbidity. These procedures have been evaluated in comparative trials and found to compare favorably to transurethral resection of the prostate (TURP). The data in the peer-reviewed medical literature suggests that these procedures may provide improvement in BPH symptoms, voiding function, and urinary retention, in addition to comparing favorably in the long-term to TURP with equally low complication rates. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have BPH and LUTS who receive the other minimally invasive treatments found in the [Policy](#) section below, the majority of evidence includes noncomparative studies. The outcomes of interest are symptoms, functional outcomes, QOL, and treatment-related morbidity. Although a few of these minimally invasive treatments have been evaluated in comparative studies, the quality of evidence was rated as very low to low certainty. Randomized controlled trials (RCTs) compared to established surgical management in the treatment of BPH are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

OBJECTIVE

The objective of this evidence review is to determine if minimally invasive treatments improve the net health outcome in individuals with benign prostatic hyperplasia and lower urinary tract symptoms.

PRIOR APPROVAL

Not applicable.

POLICY

Medically Necessary

The following procedures may be considered **medically necessary** as an alternative to open prostatectomy or transurethral resection of the prostate (TURP) for the treatment of urinary outlet obstruction due to benign prostate hyperplasia (BPH) when **ALL** the following criteria are met:

1. One of the following minimally invasive treatments is utilized:
 - Holmium laser ablation of the prostate [HoLAP];
 - Holmium laser enucleation of the prostate [HoLEP];
 - Holmium laser resection of the prostate [(HoLRP];
 - Photoselective vaporization (PVP);
 - Transurethral electro vaporization of the prostate (TUVF);
 - Transurethral microwave thermotherapy (TUMT);
 - Transurethral incision of the prostate (TUIP) with prostate ≤ 30 cc;

- Visually guided laser ablation of the prostate (VLAP), also called non-contact laser ablation of the prostate; **and**
- 2. The individual has a diagnosis of mild to moderate lower urinary tract symptoms (LUTS);
- 3. The individual has had an adequate trial of the usual prescribed BPH medications (alpha blockers, beta-3 agonists, PDE5s, anticholinergics, 5-ARIs) and is refractory or intolerant;
- 4. The individual has had appropriate testing to exclude diagnosis of prostate cancer within 12 months of the procedure.

Minimally invasive treatments not meeting the above criteria for the treatment of urinary outlet obstruction due to BPH is considered **investigational** because the evidence is insufficient to determine the technology results in an improvement in the net health outcome.

Investigational

The following minimally invasive treatments for the treatment of BPH is considered **investigational** because the evidence is insufficient to determine the technology results in an improvement in the net health outcome:

- Absolute ethanol injection (transurethral)
- Cryosurgical ablation for the treatment for BPH
- Drug-coated balloon (e.g., Optilume®)
- Endoscopic balloon dilation of the prostatic urethra
- High-intensity focused ultrasound (HIFU) (SonaBlate®)
- Histotripsy (Vortx Rx System)
- Interstitial laser coagulation (ILC)
- Placement of temporary prostatic stents (Spanner Temporary Prostatic Stent)
- Plasma Kinetic Vaporization (e.g., PlasmaKinetic™ Tissue Management System)
- Prostatic arterial embolization (PAE)
- Spring System® (Zenflow)
- Transrectal thermal therapy
- Transperineal laser ablation (TPLA) (e.g., SocrateLite)
- Transurethral needle ablation (TUNA)
- Transurethral ultrasound-guided laser incision of the prostate (TULIP)
- Water-induced thermotherapy (WIT) (also known as hot-water balloon thermoablation and thermourethral hot-water therapy)

ALL Category III codes will be considered **investigational** unless the code is explicitly addressed as a covered service in a Wellmark BlueCross BlueShield Medical Coverage Policy.

POLICY GUIDELINES

Category III codes are a set of temporary (T) codes for emerging technologies, services, and procedures that allow for data collection by the American Medical Association's (AMA). If a Category III code is available, providers must use that code instead of an unlisted or deleted Category I code. The services or procedures represented by Category III codes may not have FDA approval, may not be performed by many health care professionals across the country, and the service or procedure may not have proven clinical efficacy. Certain T codes may be addressed as a covered service in a Wellmark BlueCross BlueShield Medical Coverage Policy. But, unless there is explicit Policy criteria that specifically extends coverage to a particular Category III code, the code would generally be considered experimental, investigational, or unproven.

American Urological Association (AUA) symptom index (SI)

A questionnaire is often used to evaluate the severity of the condition. Several scoring systems have been developed to assess the subjective symptoms of BPH, including the American Urological Association (AUA) symptom index (SI). The AUA-SI test contains seven questions, and the resulting symptom score is from mild to severe. Each question is answered with a score ranging from 0 for none to 5 for severe. The symptom score (i.e., sum of the answers) is ranked as follows:

- Mild prostatism (0 to 7)
- Moderate prostatism (8 to 19)
- Severe prostatism (20 to 35)

The International Prostate Symptom Score (IPSS)

The International Prostate Symptom Score (IPSS) can be utilized to measure the severity of lower urinary tract symptoms. It is a validated, reproducible scoring system to assess disease severity and response to therapy. The IPSS is made up of 7 questions related to voiding symptoms. A score of 0 to 7 indicates mild symptoms, 8 to 19 indicates moderate symptoms and 20 to 35 indicates severe symptoms. It is not a reliable diagnostic tool for lower urinary tract symptoms (LUTS) suggestive of BPH but can be used to quantitatively measure LUTS after a diagnosis is made.

Calculator: International Prostatism Symptom Score (IPSS)

Over the past month, how often have you had a sensation of not emptying your bladder completely after you finished urinating?

- Not at all (0 points)
- Less than 1 time in 5 (1 point)
- Less than half the time (2 points)
- About half the time (3 points)
- More than half the time (4 points)
- Almost always (5 points)

Over the past month, how often have you had to urinate again less than 2 hours after you finished urinating?

- Not at all (0 points)
- Less than 1 time in 5 (1 point)
- Less than half the time (2 points)
- About half the time (3 points)
- More than half the time (4 points)
- Almost always (5 points)

Over the past month, how often have you found you stopped and started again several times when you urinated?

- Not at all (0 points)
- Less than 1 time in 5 (1 point)
- Less than half the time (2 points)
- About half the time (3 points)
- More than half the time (4 points)
- Almost always (5 points)

Over the past month, how often have you found it difficult to postpone urination?

- Not at all (0 points)
- Less than 1 time in 5 (1 point)
- Less than half the time (2 points)
- About half the time (3 points)
- More than half the time (4 points)
- Almost always (5 points)

Over the past month, how often have you had a weak urinary stream?

- Not at all (0 points)
- Less than 1 time in 5 (1 point)
- Less than half the time (2 points)
- About half the time (3 points)
- More than half the time (4 points)
- Almost always (5 points)

Over the past month, how often have you had to push or strain to begin urination?

- Not at all (0 points)
- Less than 1 time in 5 (1 point)
- Less than half the time (2 points)
- About half the time (3 points)
- More than half the time (4 points)
- Almost always (5 points)

Over the past month, how many times did you most typically get up to urinate from the time you went to bed at night until the time you got up in the morning?

- Not at all (0 points)
- Less than 1 time in 5 (1 point)
- Less than half the time (2 points)
- About half the time (3 points)
- More than half the time (4 points)
- Almost always (5 points)

Coding

See the [Codes](#) table for details.

BACKGROUND

BPH is a common condition in older men, affecting to some degree 40% of men in their 50s, 70% of those between ages 60 and 69, and almost 80% of those ages 70 years and older. Benign prostatic hyperplasia is a histologic diagnosis defined as an increase in the total number of stromal and glandular epithelial cells within the transition zone of the prostate gland. In some men, BPH results in prostate enlargement which can, in turn, lead to benign prostate obstruction and bladder outlet obstruction, which are often associated with LUTS including urinary frequency, urgency, irregular flow, weak stream, straining, and waking up at night to urinate. Lower urinary tract symptoms are the most commonly presenting urological complaint and can have a significant impact on quality of life.

BPH does not necessarily require treatment. The decision on whether to treat BPH is based on an assessment of the impact of symptoms on quality of life along with the potential side effects of treatment. Options for medical treatment include alpha-1-adrenergic antagonists, 5-alpha-reductase inhibitors, anticholinergic agents, and phosphodiesterase-5 inhibitors. Medications may be used as monotherapy or in combination.

Individuals with persistent symptoms despite medical treatment may be considered for surgical treatment. The traditional standard treatment for BPH is transurethral resection of the prostate (TURP). TURP is generally considered the reference standard for comparisons of BPH procedures. Several minimally invasive treatments have been developed, see [Policy](#) regarding the treatments discussed in this evidence review.

Regulatory Status

The AquaTherm device, formerly known as the Thermoflex™ Water-Induced ThermoTherapy System (ACMI, Southborough, MA, previously Argomed, Inc., Cary, NC) is a catheter-based thermal therapy device for the treatment of symptoms due to urinary outflow obstruction secondary to BPH. FDA 510(k) class II approval was received in 1999.

The Indigo® OPTIMA Laser System (Ethicon Endo-Surgery, Inc., Cincinnati, OH) was noted by the FDA (December 2001) to be substantially equivalent to the Indigo LaserOptic Treatment System which received FDA clearance in December 1997. It is intended to be used in the non-contact mode to photocoagulate, vaporize/ablate soft tissue (muscle, connective tissue, organ) and for cutting, incision, excision, and for coagulation in the contact mode for open/closed surgical procedures. The Diffuser Tip Fiberoptic is intended for ILC treatment of BPH.

In July 2003, the PlasmaKinetic Superpulse System (Gyrus, Maple Grove, MN) received 510(k) premarket notification (K031085) that the device is substantially equivalent to predicate devices and is safe and effective in its intended use. It is intended for use for ablation, removal, resection and coagulation of soft tissue and where associated hemostasis is required. Predicate devices are the PlasmaKinetic Generator, the PlasmaKinetic Endourology Generator, and the Endourology Axipolar Resectoscope Electrode

In March 2012, the Visual-ICE Cryoablation System (Galil Medical Inc., Arden Hills, MN) was granted FDA approval through the 510(k) process (K113860) for the indication of cryoablative tissue destruction and can be useful in numerous surgical procedures including prostate tissue destruction for the treatment of benign prostatic hypertrophy. The system is computer controlled and utilizes compressed argon gas that circulates through closed tipped needles to achieve tissue freezing.

In October 2015, the FDA granted a de novo classification for the SonaBlate® 450 (SonaCare Medical, LLC, Charlotte, NC) which is a “high intensity ultrasound system for prostate tissue ablation is a prescription device that transmits high intensity therapeutic ultrasound (HITU) energy into the prostate to thermally ablate a defined, targeted volume of tissue, performed under imaging guidance. This classification does not include devices that are intended for the treatment of any specific prostate disease and does not include devices that are intended to ablate non-prostatic tissues/organs.”

In January 2016, a temporary prostatic stent, the Spanner (SRS Medical, North Billerica, MA), received premarket approval (PMA) from the FDA based on a multicenter, prospective, randomized clinical trial designed to evaluate the safety and effectiveness of The Spanner to manage LUTS and bladder emptying following TUMT treatment after an initial period of catheterization. Based on the study results, the FDA

indicated the device is intended for temporary use (up to 30 days) to maintain urine flow and allow voluntary urination in patients following minimally invasive treatment for benign prostatic hyperplasia (BPH) and after initial post-treatment catheterization.

In June 2017, the FDA granted a de novo classification to the intravascular implant, Embosphere Microspheres (BioSphere Medical, S.A., France), as a class II biocompatible PAE device for use as a minimally invasive treatment for symptomatic BPH.

In 2018, the FDA granted 510(k) approval (K181510) for the Echolaser X4 device (El.En Electronic Engineering Spa, Calenzano, Italy) which is “intended for use in cutting, vaporization, ablation and coagulation of soft tissue in conjunction with endoscopic equipment (including laparoscopies, hysteroscopes, bronchoscopes, gastroscopes, cystoscopes and colonoscopies), in incision/excision, vaporization, ablation and coagulation of soft tissue in contact and non-contact open surgery (with or without a hand piece), and in the treatment and/or removal of vascular lesions (tumors)” (FDA, 2018b). In May 2022, the FDA granted 510(k) approval (K213594) for the SoracteLite the Echolaser X4 thermal ablation device proposed for the treatment of urological disorders including BPH.

In May 2018, the FDA gave 510(k) approval (K181153) for the ICEfx Cryoablation System (Galil Medical Inc., Arden Hills, Minnesota) for the indication of “use as a cryosurgical tool in the fields of general surgery, dermatology, neurology (including cryoanalgesia), thoracic surgery (with the exception of cardiac tissue), ENT, gynecology, oncology, proctology, and urology.” The FDA approval notice includes “urology ablation of prostate tissue in cases of prostate cancer and Benign Prostate Hyperplasia (BPH)” as a specific indication.

In December 2021, the Optilume® Urethral Drug Coated Balloon (DCB) (Urotronic, Inc) received premarket approval (PMA) from the FDA (P210020). “The device is used to treat patients with obstructive urinary symptoms associated with anterior urethral stricture. It is designed to be used in adult males for urethral stricture of 3cm or less in length.” FDA product code QRH.

The Spring System® (Zenflow, Inc.) is a nitinol expander device which is a minimally invasive procedure that gently props open the urethral opening to restore urinary flow for the treatment of individuals with BPH. As of October 2025, the Spring System (Zenflow Inc), has not received FDA approval.

RATIONALE

This evidence review was created in July 2010 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through October 2025.

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and

conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Minimally Invasive Treatments for Benign Prostatic Hyperplasia (BPH)

Clinical Context and Therapy Purpose

The purpose of minimally invasive treatments in individuals who have lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH) is to provide a treatment option that is an alternative to or an improvement on existing therapies such as medical management or transurethral resection of the prostate (TURP).

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals who are experiencing LUTS without a history suggesting non-BPH causes of the symptoms and who do not have a sufficient response to medical therapy or are experiencing significant side effects with medical therapy.

Interventions

The therapy being considered is minimally invasive treatments, see [Policy](#).

Comparators

The following practices are currently being used to treat BPH in this setting:

- Conservative treatment, including watchful waiting and lifestyle modifications
- Pharmacotherapy (alpha blockers, beta-3 agonists, PDE5s, anticholinergics, 5-ARIs)
- Transurethral resection of the prostate (TURP) which is generally considered the reference standard for comparisons of BPH procedures.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, health status measures, QOL, and treatment-related morbidity.

The International Prostate Symptom Score (IPSS) is used to assess the severity of BPH symptoms. The first 7 questions address urinary frequency, nocturia, weak urinary stream, hesitancy, intermittence, incomplete emptying, and urgency each on a scale of 0 to 5. The total score, summed across the 7 items measured, ranges from 0 (no symptoms) to 35 (most severe symptoms). A decrease in score indicates improvement.

Several health status measures are used to evaluate symptoms relevant to BPH and adverse events of treatment for BPH, including urinary symptoms, urinary dysfunction measured by peak urinary flow rate

(Qmax), ejaculatory dysfunction, overall sexual health, and overall quality of life. Qmax is measured by uroflowmetry; low rates are associated with more voiding dysfunction and rates <10 mL/sec are considered obstructed. Urinary continence may be assessed via the Incontinence Symptom Index (ISI) questionnaire. Erectile and ejaculatory function is assessed in sexually active men only. Scales include the International Index of Erectile Function and the Male Sexual Health Questionnaire.

Quality of life is assessed with various scales including the IPSS-QoL.

Both short-term (up to 12 months) and long-term (12 months and longer [demonstrating durability to at least 2 years if preferred]) outcomes should be assessed. Treatment-related morbidity can also be assessed in the immediate post-procedure period.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Medically Necessary Procedures

Several minimally invasive treatments have been proposed as an alternative to TURP including holmium laser ablation of the prostate [HoLAP]), holmium laser enucleation of the prostate [HoLEP], holmium laser resection of the prostate [(HoLRP], photoselective vaporization (PVP), transurethral electro vaporization of the prostate (TUVF), transurethral microwave thermotherapy (TUMT), transurethral incision of the prostate (TUIP) and visually guided laser ablation of the prostate (VLAP). These minimally invasive treatments have been evaluated in comparative trials and found to compare favorably to TURP. The data in the peer-reviewed medical literature suggests that these procedures may provide improvement in BPH symptoms, voiding function, and urinary retention, in addition to comparing favorably in the long-term to TURP with equally low complication rates. See [Practice Guideline and Position Statements](#).

Investigational Procedures

Absolute Ethanol Injections Transurethral

Absolute Ethanol Injection is a minimally invasive procedure that can be performed in an outpatient setting and has been proposed as a treatment for BPH. Ethanol injection is performed using dehydrated ethanol injected with a flexible injection needle through the side channel of a cystoscope and into the targeted tissue. The result is coagulation necrosis (chemoablation) aimed at destroying the enlarged tissue.

RCT data are lacking regarding the safety and effectiveness of absolute ethanol injection compared to standard therapy for the treatment of BPH. Two small prospective nonrandomized studies without comparators and a case series study totaling 123 patients demonstrated improvements in International Prostate Symptom Score (IPSS), quality of life scores, and significant differences in peak flow volumes and post void residual after therapy.

Section Summary: Absolute Ethanol Injections

Based on the review of the current peer reviewed medical literature RCTs are lacking regarding the safety and effectiveness of absolute ethanol injection compared to standard therapy for the treatment of BPH. Further RCTs are needed with long term follow-up to determine the safety and efficacy of absolute ethanol injection in the treatment of BPH.

Cryosurgical Ablation

Cryosurgical ablation for treatment of BPH there are no published controlled or uncontrolled studies evaluating this procedure for treating BPH identified.

Section Summary: Cryosurgical Ablation

Based on the current peer reviewed medical literature there are currently no published controlled or uncontrolled studies evaluating this procedure for treating BPH. RCTs with long term outcomes are needed to determine the safety and efficacy of this procedure for the treatment of LUTS secondary to BPH.

Drug Coated Balloon (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.

Systematic Review

In 2024, Estaphanous et al conducted a systematic review to evaluate the efficacy and safety of Optilume® drug coated balloon (DCB) for males with urethral stricture disease with moderate to severe lower urinary symptoms (LUTs). Reviewers searched PubMed, Scopus, Google Scholar and the Cochrane Library through November 2024 and identified 7 studies (one RCT [VanDyke 2024 ROBUST III, 2 year follow-up]), three prospective cohort studies (DeLong 2024 ROBUST I [5 year follow-up], Alhamdani 2024, DeLong 2022 ROBUST II [1 year follow-up]) and three retrospective cohort studies (Ballesteros Ruiz 2024, Dabbas 2024, Castellucci 2023) that included a total of 457 participants. In the ROBUST III study (VanDyke 2024) Optilume was compared to control group (traditional endoscopic management). Actual patient characteristics except for age were not detailed the authors stated “each study reported essential details, including patient demographics, specifics of the intervention, follow-up duration and outcome measures. Follow-up duration ranged from three months to five years, with most strictures located in the anterior bulbar urethra and measuring under 3 cm in length.” The primary

outcome measures included significant reductions in symptom scores, as measured by the International Prostate Symptom Score (IPSS), and improvements in urinary flow rates (QMax). Secondary outcome measures examined the rates of stricture recurrence and complications. A meta-analysis using a fixed-effects model was conducted due to low heterogeneity ($I^2 = 5\%$). The analysis showed a statistically significant improvement in IPSS scores across all seven studies following Optilume DCB treatment, with a mean reduction of 13 points (95% CI: -15.8 to -10.3; $p < 0.0001$). A fixed-effects model was applied due to minimal heterogeneity ($I^2 = 8\%$). The meta-analysis revealed a statistically significant improvement in six of the studies included in the QMax, with a mean increase of 10.11 mL/s (95% CI: +7.8 to +12.4; $p < 0.0001$). Recurrence rates were reported across all 7 studies with follow-up durations ranging from 3 months to five years. The mean recurrence rate was 19.17% (95% CI: 15.2% to 23.1%; $p < 0.0001$), corresponding to a mean free from re-intervention rate of approximately 80.83%. In the Robust III trial (VanDyke (2024) Optilume group demonstrated a 77.8% recurrence free rate at two years versus control group's 23.6% recurrence free rate at same time point. Complication rates were reported across five studies, and the weighted average complication rate was 9.5%. The most reported complications were transient dysuria, hematuria, urinary tract infections and temporary urinary retention. No severe complications were reported. Limitations included in majority of studies were short follow-up periods and only included one RCT which restricts comparing data with other treatments such as urethroplasty or minimally invasive procedures such as dilation and direction vision internal urethrotomy (DVIU). The authors recommended "larger RCTs with extended follow-up are needed to further confirm long-term efficacy and safety."

Randomized Controlled Trial

We identified no additional RCTs not already included in the Estaphanous 2024 SR summarized above. Below is a summary of the initial one-year outcomes from the ROBUST-III RCT, which the longer-term 2-year outcomes are included in the results of the Estaphanous 2024 SR.

In 2022, Elliott et al evaluated the safety and efficacy of Optilume® paclitaxel-coated balloon versus urethral dilation and/or direct vision internal urethrotomy (DVIU) in a multi-center, single-blind, randomized, controlled trial (ROBUST III study) in the management of recurrent anterior urethral strictures with moderate to severe lower urinary symptoms (LUTs). A total of 127 subjects were enrolled at 22 sites (21 sites in United States and 1 site in Canada). Eligible patients were adult males with anterior stricture ≤ 12 Fr in diameter and ≤ 3 cm in length, at least 2 prior endoscopic treatments, International Prostate Symptom Score (IPSS) > 11 and maximum flow rate < 15 mL per second. The primary endpoint was anatomical success in participants who could pass a 16Fr flexible cystoscope or a 14Fr catheter through the treated area at 6 months. Additional outcomes included average Qmax, IPSS, IPSS quality of life (QOL), and International Index of Erectile Function (IIEF) over time. Freedom of repeat intervention (repeat dilation, DVIU or urethroplasty) was evaluated at 1-year. Participants were randomized in 2:1 allocation of treatment versus control stratified by prior pelvic radiation therapy (yes/no) and number of prior endoscopic treatments (< 5 versus ≥ 5). Demographic and stricture characteristics were similar between randomized groups. Strictures were mostly bulbar (92.1%) and averaged 1.7 cm in length. Participants had an average of 3.6 prior dilations with 18.1% (23/127) having ≥ 5 prior treatments. Randomized participants were blinded to treatment for 6 months which was the primary endpoint. Unblinding could occur if medically necessary (recurrent stricture requiring intervention). The treatment group received Optilume® DCB ($n=79$; average age 58.7 with majority individuals white [65]) and control group ($n=48$; average age 60.6 with majority individuals white [39]) included serial dilation with urethral sounds, DVIU, balloon dilation or a combination (lumen size was not prespecified). Participants in the control group were allowed to cross over to the randomized arm with stricture recurrence confirmed via recurrent symptoms, decreased flow and stricture diameter 12Fr measured by urethrogram before 12-months post-procedure. Follow-up post-procedure occurred when foley removed (2-5 days in both groups), 30-days, 3 and 6-months and 1-year. For results see Tables 1 and 2 below. Adverse events

included urinary tract infection, post procedural hematuria and dysuria. Limitations included surgeons were not blinded to treatment which might have biased interpretation of cystoscopic findings and their decision to proceed with repeat treatment, patients were unblinded after 6-months which could have biased the secondary outcomes, and primary outcomes were missing on 7 control and 12 Optilume® DCB participants. The authors noted these participants will continue to be followed for 5 years (see Estaphanous 2024).

Table 1. Primary Efficacy End Points

End Point	Standard of Care	Optilume® DCB	Difference* (95% CI)	p Value*
No. pts	48	79		
% Stricture-free (No./total No.)	26.8 (11/41)	74.6 (50/67)	44.4 (27.6-61.1)	<0.0001
No. Subject Accountability				
Pass urethral lumen test at 6 months	11	50		
Failed urethral lumen test at 6 months +	12	15		
Repeat intervention prior to 6 months +	18	2		
Missing cystoscopy at 6 months	7	12		

*Estimates of the difference (Optilume versus control), 95% CI and 1-sided p value are based on the model-based estimates resulting from multiple-imputation of missing data.

+Urethral lumen test included 105 subjects assessed with 16Fr flexible cystoscope and 3 with 14Fr foley catheter.

+ Repeat intervention includes participants receiving additional DVIU, dilation or urethroplasty, including those in control arm with confirmed stricture recurrence (lumen < 12Fr by urethrography with recurrent symptoms) who opted to cross over to receive treatment with Optilume DCB.

Table adapted from Elliott et al 2022.

Table 2. Secondary Outcome Measures

Measure	Baseline	30 Days	3 Months	6 Months	1 Year
Mean±SD IPSS (No. pts):					
Optilume	22.0±6.8 (79)	7.6±5.7 (78)	7.4±5.8 (74)	8.3±6.2 (71)	9.0±7.1 (67)
Standard of Care	22.8±7.0 (47)	9.5±7.4 (47)	12.4±9.2 (45)	15.4±9.6 (43)	19.9±7.5 (42)
Mean±SD IPSS – QOL (No. pts):					
Optilume					

Measure	Baseline	30 Days	3 Months	6 Months	1 Year
Standard of Care	4.5±1.3 (79) 4.7±1.2 (47)	1.7±1.4 (78) 2.0±1.6 (47)	1.6±1.4 (74) 2.7±1.8 (45)	1.7±1.3 (71) 3.4±1.8 (43)	1.9±1.5 (67) 4.0±1.3 (42)
Mean±SD ml/sec Qmax No. pts):					
Optilume	7.6±3.4 (78)	18.3±9.1 (75)	18.6±10.9 (71)	16.6±8.9 (67)	15.5±9.0 (65)
Standard of Care	7.4±3.5 (47)	15.8±8.5 (44)	13.3±9.3 (39)	11.1±7.6 (44)	7.6±4.0 (41)
Mean±SD ml PVR urine (No. pts):					
Optilume	109.8±116.9 (77)	75.6±86.2 (75)	103.4±134.4 (70)	73.1±117.7 (67)	94.6±121.8 (66)
Standard of Care	133.8±155.1 (47)	79.1±87.3 (45)	113.4±124.2 (41)	141.4±194.1 (44)	181.5±201.7 (42)
Mean±SD IIEF (No. pts):					
Optilume	5.8±2.9 (72)	5.9±2.8 (75)	6.6±2.7 (71)	6.5±2.8 (68)	6.9±3.0 (59)
Standard of Care	6.0±3.2 (46)	5.7±3.0 (45)	6.1±3.0 (40)	6.6±3.2 (30)	5.8±2.7 (13)

Table adapted from Elliott et al 2022

Observational Studies

In 2023, Pichardo et al reported on the results through 2-years of post-procedure follow-up of the EVEREST-I study (Kaplan et al 2021). This open-label, single-arm study enrolled 80 men with moderate-severe lower urinary tract symptoms (LUTS) related to benign prostatic hyperplasia (BPH) who were treated with Optilume® BPH Catheter System. At 2-years there were 68 subjects evaluated (6 with missed visits, 2 with remote visit with no efficacy assessments, and 4 early exists [n=80]). In these 68 subjects 85.3% (58/68) experienced an improvement $\geq 40\%$ in IPSS and 47.1% (32/68) reported improvement in IPSS by at least 75% which was consistent with responder rates at 1-year of 81.3% and 50.7% for $\geq 40\%$ and $\geq 75\%$ improvement, respectively. The responder rate did not differ significantly based on the threshold utilized for clinical significance 89.7% (61/68) for a threshold of $\geq 30\%$ improvement in IPSS and 92.6% (63/68) for a threshold of 3-point improvement in IPSS. The average peak flow rate Qmax at 2-years was not significantly changed from year one which was reduced from 63.1 mL at baseline to 45.0 mL at 2-years ($p=0.263$). The mean IPSS QOL improved from 4.6 at baseline to 1.3 at 1 year and 1.6 at 2-years ($p<0.001$). There was a total of 123 adverse events (AEs) reported in 54 subjects through 2 years, with 10 events occurring between 12 and 24 months. The reviewers advised these outcomes may be promising but this study had limitations to include no control comparator group, and “further studies are needed to establish the safety and efficacy of Optilume® BPH Catheter System in the management of LUTS related to BPH.

In 2021, Kaplan et. al. reported on the first report of 1-year outcomes of the EVEREST-I study evaluating the safety and efficacy of the Optilume® BPH Catheter System, a prostatic paclitaxel-coated balloon catheter system, for the treatment of lower urinary tract symptoms (LUTS) related to benign prostatic hyperplasia (BPH). Subjects were men >50 years old with moderate-to-severe LUTS secondary to BPH, peak urinary flow rate of 5–15 ml/s, prostatic urethra length 30–55 mm, and prostate volume 20–80 g. All were treated with the Optilume® BPH Catheter System and followed at Foley removal, 2 weeks, 30 days, 3, 6, and 12 months after treatment. The primary endpoint was the proportion of subjects with ≥40% improvement in International Prostate Symptom Score (IPSS). The rate of post procedural complications was evaluated. Eighty subjects were treated at six sites in Latin America and 75 completed the 1-year follow-up. The percent of subjects with an improvement ≥40% in IPSS from baseline was 81% at 3 months and 1 year. IPSS improved from 22.3 at baseline to 7.9 at 1 year, Qmax improved from 10.9 to 18.4 ml/s, and IPSS QoL improved from 4.6 to 1.3. Post-procedural complications included common urologic events, and the rate of complications was significantly impacted by device diameter. Study limitations include the lack of a control group. A randomized clinical trial is currently ongoing to confirm the findings. This initial experience helped inform development of the technology to improve outcomes. The authors concluded Clinical data from the EVEREST-I study showed that treatment for obstructive BPH with Optilume® BPH Catheter System provides clinically meaningful benefits, with rapid improvement in LUTS severity and voiding function within 2 weeks that were sustained through 1 year. The therapy had an acceptable safety profile and improved subject's QoL. This new technological approach shows promise as an effective minimally invasive treatment alternative to medication or surgical interventions without the necessity of a permanent implant or tissue ablation/removal.

In 2020 Virasoro et al examined the safety and preliminary efficacy of the Optilume® paclitaxel-coated balloon for the treatment of recurrent urethral stricture in a single-arm, prospective, open-label study ROBUST 1 study. Men with bulbar urethral strictures of less than or equal to 2 cm with 1 to 4 prior endoscopic treatments and moderate to severe lower urinary symptoms (LUTs) (International Prostate Symptom Score (IPSS) ≥13, and maximum flow rate < 10 [Qmax]) were enrolled at 4 study sites after ethics committee approvals. All subjects (men average age 50.7 years with the majority [83%] Hispanic/Latino ethnicity) were treated with mechanical balloon dilation or direct visualization internal urethrotomy prior to drug-coated balloon treatment. Patients were evaluated at 2 to 5 days, 14 days, 3, 6, and 12-months post-treatment. The primary safety endpoint was serious complications through 90 days post-procedure. The preliminary efficacy endpoint was anatomic success, defined as urethral lumen of greater than or equal to 14-French at 12 months. Secondary endpoints included IPSS, sexual function (International Index of Erectile Function [IIEF]), Qmax, post-void residual urine volume (PVR), and pain (Visual Analog Scale, [VAS]) A total of 53 subjects were enrolled and treated; 46 completed the 12-month follow-up; 43 % of men had undergone greater than 1 previous dilation; the mean for the overall study population was 1.7 prior dilations. There were no serious AEs related to the treatment within 90 days. Anatomic success was achieved in 32/46 (70 %; 95 % CI: 54 to 82 %) at 12 months. The 14 failures included 7 cystoscopic recurrences, 5 re-treatments, and 2 patients who exited the study early due to symptom recurrence. Secondary endpoints: the baseline IPSS ranged from 15–34 with a mean of 25.2 (±4.5), and IPSS quality of life (QOL) ranged from 2–6 with a mean of 4.9 (±0.9) with one year no statistically significant improvement in mean IPSS (4.9±5.6) and IPSS-QOL (0.8±1.1) compared to baseline (p<0.001); mean IIEF satisfaction scores were 6.5 (±2.6) at baseline and 7.8 (±2.6) one-year post-treatment; mean Qmax improved from 5.0 ml/sec (baseline) to 23.6, 24.2, 22.2, 20.5, and 19.5 ml/sec at the 14-, 30-, 90-, 180-, and 365- day follow-ups; the average PVR decreased from 141.0 ml (baseline) to 27.3 ml and 26.7 ml at the 180- and 365-day follow-ups, respectively; and a mean VAS score of 2.9 (±2.87) and mean VAS scores decreased to 0.6 (±1.0) and 0.9 (±1.9) at 14 and 30 days (most patients experienced only minor pre-procedure pain related to their stricture disease). Limitations included small sample size, excluding individuals with conditions that cause urethral strictures with a

higher recurrence rate (penile strictures, bladder neck contractures, previous pelvic radiation or history of lichen sclerosus), no control arm and lack of long-term follow-up. The researchers provided that five-year results will be reported when become available (see Estaphanous 2024).

Section Summary: Drug Coated Balloon (Optilume®)

Based on the current peer reviewed medical literature which includes systematic review and RCTs, there is only one RCT the ROBUST III study which compares the use of Optilume® DCB with standard endoscopic treatment. While studies may show promise additional well designed RCTs with larger sample sizes and longer follow-up are needed to determine the efficacy and safety of Optilume® BPH Catheter System in the management of LUTS related to BPH.

Endoscopic Balloon Dilation

Endoscopic balloon dilation for treatment of BPH involves the insertion of a balloon catheter tip through the urethra into the prostatic channel where it is inflated to stretch the urethra narrowed by the prostate. Based on the research, endoscopic balloon dilation has been inadequately studied with limited controlled trials and few long-term studies.

Section Summary: Endoscopic Balloon Dilation

Based on the research, endoscopic balloon dilation has been inadequately studied with limited controlled trials, few long-term studies, and “a fallout in enthusiasm” for this treatment.

High-Intensity Focused Ultrasound (HIFU)

High-intensity focused ultrasound (HIFU) is a procedure which uses a small probe to produce bursts of ultrasound that creates coagulation necrosis in a specific area of tissue. Frequencies range from 4–10 MHz, although 4 MHz is most frequently used. HIFU devices use imaging ultrasound for treatment planning and monitoring, and they deliver targeted high-intensity ultrasound that rapidly elevates the temperature in a precise focal zone. The increased tissue temperature is designed to kill excess prostate tissue (in the case of BPH). The same probe can be used for imaging, which allows both diagnostic and therapeutic testing at the same time.

Systematic Review

In 2024, Garcia-Becerra et al conducted a systematic review to evaluate the safety and efficacy of high-intensity focused ultrasound (HIFU) in the treatment of benign prostatic hyperplasia (BPH) with lower urinary tract symptoms (LUTS) effecting the quality of life (QOL) in older men. Reviewers searched PubMed, Google Scholar, Cochrane Central, and ClinicalTrials.gov databases from 1994-2023. Twelve studies were included (6 clinical trials [Madersbacher 1994, Uchida 1995, Nakamura 1995, Madersbacher 1996, Madersbacher 1997, Uchida 1998] and 6 observational studies [Ebert 1994, Bihle 1994, Mulligan 1997, Sullivan 1997, Schatzl 2000, Lu 2007]) that included 522 patients; all single-group noncomparative. The inclusion criteria focused on peer reviewed studies with more than 10 male patients utilizing HIFU for BPH with pre- and post-treatment follow-up parameters (Qmax, International Prostate Symptom Score [IPSS], postvoid residual volume [PVR]), prostate volume and reported complication). The primary outcomes within a period of 12 months of follow-up showed a Qmax improvement from a baseline of 3.20 ml/s at 3 months to 6.22 ml/s at 12 months and an IPSS reduction from baseline to -11.47 points at 3 months that then remained stable at 12 months, reflecting an important increase in quality of life. Her

PVR decreased by -28.62 ml at 1 month and progressed to a reduction in volume of -54.18 ml at 12 months. Reported complications included transient hematuria (THU), transient hematospermia (THS), transient urinary retention (TUR), post-treatment transurethral resection of the prostate (due to poor clinical improvement), infections, enterovesical fistulas (EFs), and stenosis. Limitations included observational studies with no control groups, small sample sizes and lack of long-term follow-up.

Section Summary: High-Intensity Focused Ultrasound (HIFU)

No comparative studies were identified for HIFU. While results from single-group noncomparative studies may be promising, study limitations include lack of control comparator group, and well-designed RCTs are needed with long term outcomes to determine safety and efficacy of HIFU for the management of LUTS in the treatment of BPH.

Histotripsy

Histotripsy is an extracorporeal ultrasound technology that has been proposed to treat BPH. Histotripsy is a form of focused ultrasound therapy that utilizes cavitation mechanisms to produce tissue necrosis in prostatic tissue.

There are scarce data in the published peer-reviewed scientific literature to support the safety and effectiveness of histotripsy for the treatment of BPH. At this time the role of this therapy has not yet been established.

Section Summary: Histotripsy

There are scarce data in the published peer-reviewed scientific literature to support the safety and effectiveness of histotripsy for the treatment of BPH. At this time the role of this therapy has not yet been established.

Interstitial Laser Coagulation

Interstitial laser coagulation (ILC) of the prostate by the transurethral route has been attempted using several laser and delivery devices. The laser enters the prostate and tissue is coagulated. Intraprostatic lesions reabsorb and the tissue atrophies. Consequently, some volume reduction occurs.

Indigo 830e has been studied in the United States; however, its role in treating lower urinary tract symptoms has yet to be defined. The lack of randomized controlled studies comparing ILC to other approaches has resulted in no consensus on the ILC technique.

Section Summary: Interstitial Laser Coagulation

At present there is insufficient evidence in the published peer-reviewed scientific literature to support the effectiveness of interstitial laser coagulation (ILC); its role in the treatment of BPH has not yet been established.

Plasma Kinetic Vaporization

The PlasmaKinetic™ Tissue Management System (Gyrus ACMI, Southborough, MA) uses plasma energy to vaporize tissue with minimal thermal spread and enhanced hemostasis.

There are scarce data in the published, peer-reviewed scientific literature regarding the safety or effectiveness of this therapy and its role in the treatment of BPH has not yet been established.

Section Summary: Plasma Kinetic Vaporization

Based on review of the current peer reviewed medical literature there is limited data published regarding the safety or effectiveness of this therapy and its role in the treatment of BPH has not yet been established.

Placement of Temporary Prostatic Stents (Spanner Temporary Prostatic Stent)

The Spanner Prostatic Stent (SRS Medical) is a temporary urinary stent that reduces urethral resistance typically caused by BPH and allow voluntary urination and maintenance of urine flow without the use of medication, catheterization, or surgery. The Spanner is intended to remain in place for up to 30 days for three consecutive uses (i.e., 3 devices used for a total of 90 days).

Hayes completed an annual review of the evolving evidence review (April 2025) for the Spanner Prostatic Stent (SRS Medical) for the treatment of male bladder outlet obstruction following transurethral treatment of the prostate using transurethral microwave thermotherapy (TUMT). Review of the peer-reviewed medical literature identified no eligible systematic reviews and found two clinical studies reported in 3 publications which included an RCT (1 reported in 2 publications) compared to standard of care (Shore et al 2007 and Dineen et al 2008) and a prospective, pretest-posttest (Kessarar et al 2017) that were considered fair quality and poor quality. The current studies may show promise in providing 1 to 4 weeks posttreatment symptom relief and improved urinary function, but it is not clear whether the benefits outweigh the potential risks. Also, no studies were identified that assessed the use of Spanner Prostatic Stent with other minimally invasive treatments other than TUMT.

Section Summary: Placement of Temporary Prostate Stents (Spanner Temporary Prostatic Stent)

Based on review of the current peer reviewed medical literature there is limited data published regarding the safety and effectiveness of the use of temporary prostate stents i.e., Spanner Prostatic Stent used after transurethral prostate treatments typically caused by BPH. While the current evidence may be promising the current studies have only assessed the use of this device following TUMT and it is not clear whether the benefits outweigh the potential risks. The safety and effectiveness and role in the treatment of BPH has not yet been established. Additional RCTs are needed comparing Spanner Temporary Prostatic Stent with other minimally invasive treatments in the management of BPH to determine efficacy and safety of his device.

Prostatic Arterial Embolization

Prostatic arterial embolization (PAE) is proposed as a minimally invasive procedure and as an alternative to TURP or open prostatectomy for the treatment of BPH. PAE for BPH has been proposed to reduce the blood supply of the prostate gland, causing some of it to undergo necrosis with subsequent shrinkage. The procedure is performed under local anesthesia and sedation using a percutaneous transfemoral approach by an interventional radiologist, in consultation with the urologist. The arterial occlusion may be achieved through the use of polyvinyl alcohol particles, coil embolizers, or microspheres.

Systematic Reviews

Hayes completed an annual review of the health technology assessment (May 2025) regarding prostatic artery embolization (PAE) for treatment of benign prostatic hyperplasia (BPH) refractory to medical management. Overall, the evidence is considered low quality due to a limited comparison with other minimally invasive therapies. The current evidence (8 RCTs, 1 prospective comparative cohort study and 3 retrospective studies; 7 of these studies are included in Jung et al 2022 below) has found PAE only compared to surgical procedure TURP. When compared to TURP, PAE did provide some short-term benefits regarding reduced blood loss and less urinary catheterizations, however, TURP was found to provide greater long-term benefits to include better control of urinary symptoms and reduction of prostate size. PAE was found to be reasonably safe with low incidence of serious complications and somewhat safer than TURP, but the evidence is currently insufficient evaluating the safety of PAE compared to other minimally invasive procedure such as laser enucleation and prostate urethral lift (PUL). Also, patient selection criteria for PAE have not been established. Additional RCTs with > 2 years of follow-up are needed to evaluate the long-term efficacy and safety of PAE to other minimally invasive therapies for the treatment of BPH.

Jung et al. (2022) conducted a Cochrane systematic review of randomized controlled trials and prospective cohort studies to evaluate the effects of prostate artery embolization (PAE) on the treatment of lower urinary tract symptoms in men with benign prostatic hyperplasia (BPH). Nine studies (Abt 2021, Insausti 2020, Pisco 2020, Radwan 2020, Zhu 2018, Ray 2018, Soluyanov, Carnevale 2016, Gao 2014) comparing either PAE to TURP (7 studies; n=300) or PAE to sham (2 studies; n=120) were included in the review. The primary outcome measured was the International Prostate Symptom Score (IPSS). Secondary outcomes included were maximal flow rate (Qmax), post void residual (PVR), quality of life (QoL), chronic prostatitis symptoms index, prostate volume, prostate-specific antigen (PSA), and the International Index of Erectile Function-5 questionnaire (IIEF-5). Short (i.e., ≤ 12 months) and long-term (i.e., 13–24 months) follow-up data showed little to no difference in the improvement of IPSS, QoL, or erectile function scores compared to TURP. The quality of evidence was rated very low to low certainty. The authors were uncertain about major adverse events but concluded that PAE results in an increase in retreatment rates compared to TURP. The quality of evidence used to reach this conclusion was rated moderate. The authors concluded that the evidence for the use of PAE for the treatment of LUTS in men with BPH should be better informed by larger studies with longer follow-up.

Malling et al. (2019) conducted a systematic review and meta-analysis of 10 studies (randomized controlled trials and prospective studies) (n=1,046) to review the efficacy and safety of prostate artery embolization (PAE) in the treatment of benign prostatic hyperplasia (BPH) with lower urinary tract symptoms (LUTS). The number of patients in each study ranged from 22-630 and the mean age was 68.6 years. Studies evaluating the efficacy of PAE to treat BPH were included. Studies with less than ten participants, short-term follow-up (< 6 months) or indications for PAE other than BPH were excluded. The intervention was PAE to treat BPH and TURP served as a comparator. The primary outcome measure was mean change in the International Prostate Symptom Score (IPSS). Secondary outcome measures were quality of life (QoL), prostate volume (PV), prostate-specific antigen (PSA), post-void residual (PVR), peak urinary flow (Qmax), International Index of Erectile function (IIEF-5), complications, and technical and clinical success rates. Follow-up for nine of the studies was 12 months while one study, with an unreported number of participants, was followed for 6.5 years. Meta-analysis showed statistically significant improvement in IIEF (p=0.005) and all other outcomes (p<0.001) at 12 months follow-up. Adverse events included: transient dysuria, increased urinary frequency, post embolization syndrome, bladder ischemia, UTI, and persistent perineal pain for three months. Author noted limitations included: heterogeneity of IPSS measurement thresholds, patient selection, embolization technique, small sample

sizes, short-term follow-up, and one long-term follow-up that is based on a small sample size. Additional, high-quality studies are needed to support the safety and efficacy of PAE.

In a 2018 meta-analysis and systematic review, Zumstein et al. evaluated studies comparing PAE with TURP for patients with BPH. The authors included five studies (n=708); (Gao et al., 2014; Russo et al., 2015; Carnevale et al., 2016; Abt et al., 2018; Ray et al., 2018) with at least 12-month follow-up. The authors concluded that PAE was less effective than TURP and had less favorable IPSS scores, peak urinary flow, prostate volume reduction, and prostate void residual. In contrast, International Index of Erectile Function scores were better, and complications were fewer for PAE versus TURP. The authors reported that additional randomized controlled trials with longer follow-up periods are needed to evaluate the mid- and long-term efficacy and safety of PAE and to assess its ideal spectrum of indications, also compared to less invasive procedures such as TUMT, TUNA, or prostatic urethral lift.

Randomized Controlled Trials

Insausti et al. (2020) conducted a non-inferiority randomized controlled trial (n=45) to assess the efficacy and safety of prostate artery embolization (PAE) versus Transurethral Resection of the Prostate (TURP) in the treatment of lower urinary tract symptoms (LUTS) related to BPH. Patients were included if: age >60 years, TURP was indicated; the International Prostate Symptom Score (IPSS) was ≥ 8 , quality of life (QoL) related to LUTS was ≥ 3 , and the peak flow rate (Qmax) was ≤ 10 mL/s or urinary retention. Patients were also included if LUTS related to BPH was refractory to medical treatment for at least six months or the patient could not tolerate medical treatment. Patients were excluded if they had: advanced atherosclerosis and tortuosity of the iliac arteries, non-visualization of the prostatic artery or other accessory arteries supplying the prostate on computed tomography angiography, urethral stenosis, detrusor failure or neurogenic bladder, glomerular filtration rate of less than 30 mL/min, and the presence of prostate cancer. The intervention was PAE (n=23) performed with 300- to 500- μ m microspheres under local anesthesia. Bipolar TURP (n=22) under spinal or general anesthesia served as the comparator. Primary outcomes were changes in Qmax and IPSS score. QoL and prostate volume (PV) changes were secondary outcomes. Follow up occurred at three months, six months, and 12 months post procedure. Results showed a nonsignificant 3.31 mL/second difference in Qmax in favor of TURP ($p < 0.862$) and a 3.04-point difference in IPSS score in favor of PAE ($p = 0.080$). A significant difference was seen in QoL in favor of PAE ($p = 0.002$), and a 22.1 cm³ difference in PV in favor of TURP ($p < 0.001$). Adverse events for TURP were urethral stricture, retrograde ejaculation, erectile dysfunction, decreased ejaculatory volume, and mild hematuria. Adverse events for PAE were rectal ischemia; radiodermatitis; urinary retention, irritation, pain, discomfort; erectile dysfunction; and transient changes in the color of the penis. Author noted limitations were small sample size, patient attrition, non-blinding of patients, and short-term follow-up.

Pisco et al. (2020) conducted an RCT (n=80) to assess the safety and efficacy of prostatic artery embolization (PAE) compared with sham in the treatment of lower urinary tract symptoms (LUTS) caused by benign prostatic hypertrophy (BPH). Patients ranged in age from 48-76 years. Inclusion criteria were as follows: age greater than 45 years; maximum urine flow rate (Qmax) < 12 mL/s; prostate volume (PV) ≥ 40 cm³, and diagnosis of severe LUTS/BPH refractory to medical management. The exclusion criteria included: computed tomography (CT) angiography showing that prostatic arteries were not feasible for PAE; previous surgical or invasive prostate treatments; prostatitis or suspected prostatitis; history of prostate or bladder cancer or pelvic irradiation; active or recurrent urinary tract infections; history of neurologic condition or disease causing or impacting LUTS; advanced atherosclerosis and tortuosity of iliac and prostatic arteries; secondary renal insufficiency; large bladder diverticula or stones; detrusor failure; history of acute urinary retention; current severe, significant, or uncontrolled disease; bleeding

disorder; hypersensitivity or contraindication to tamsulosin use; mental condition or disorder that would interfere with the patient's ability to provide informed consent; participation in a study of any investigational drug or device in the previous three months; and administration of the 5-ARIs finasteride and dutasteride in the previous two week and four months respectively. The intervention was PAE (n=40) performed with 300-500 μ m microspheres. Sham PAE without embolization (n=40) served as the comparator. After six months follow-up, the sham group also underwent PAE and were then followed for another six months. Primary outcome measures included: change from baseline International Prostate Symptom Score (IPSS) and quality of life (QoL) score. The secondary outcomes measured were changes from baseline in the BPH Impact Index, the 15-item International Index of Erectile Function (IIEF-15), PV, Qmax, postvoid residual urine volume (PVR), and PSA. Follow up occurred at one, three-, and six-months post treatment. Statistically significant improvement was shown in IPSS ($p<0.0001$) and QoL ($p=0.0001$), a decrease in prostate volume of 0.06 cm³ and 17.6 cm³ in the sham and PAE groups respectively ($p=0.002$), an increase in Qmax of 2.80 ml/s and 6.82 ml/s in the sham and PAE groups respectively ($p=0.005$), an increase in PVR volume in the sham group of 8.63 ml and a decrease of 59.9 ml in the PAE group ($p=0.03$), and a decrease in PSA of 0.02 ng/dl and 1.51 ng/dl in the sham and PAE groups respectively ($p=0.01$). A statistically significant improvement was not shown in IIEF-15 scores with an increase of 5.95 and 9.53 points in the sham and PAE groups respectively ($p=0.29$). The following adverse events were reported: perineal pain, urethral pain, dysuria, ecchymosis, hematospermia, hematuria, inguinal hematoma, expelled prostate fragment, rectorrhagia, and UTI. Author noted limitations included: inclusion of severe LUTS only, the large PVs of the participants, small sample sizes, and short-term follow-up.

Observational Study

In 2024, Sapoval et al described the two year clinical outcomes regarding prostatic artery embolization (PAE) using Embosphere Microspheres (Merit Medical, South Jordan, Utah, USA) for symptomatic benign prostatic hyperplasia (BPH) in an international, multicenter, prospective trial of males with lower urinary tract symptoms (LUTS) or acute urinary retention (AUR). The mean age of the male participants was 70 years of age, either with BPH related bothersome LUTS without an indwelling bladder catheter and those with AUR due to underlying BPH with a urinary bladder catheter. Four hundred seventy-eight patients underwent PAE: LUTS cohort N=405 and AUR cohort: N=73. The primary outcome measures was the 12-month change in the International Prostate Symptom Score (IPSS) for patients referred for bothersome LUTS, or urinary catheter independence for patients treated for AUR. Secondary outcome measures included changes in IPSS at 3 and 24 months, changes in quality of life (QoL), changes in the Sexual Health Inventory for Men (SHIM) questionnaire, technical success rate, and adverse events (AEs). For patients treated for bothersome LUTS, mean total IPSS at baseline was 21.8 and decreased to 9.3, 10.6, and 11.2 at 3, 12, and 24 months following PAE, respectively (all $p<0.001$); QoL at baseline was 4.7 and decreased to 2.0, 2.1, and 2.3 at 3, 12, and 24 months, respectively (all $p<0.001$). The mean SHIM score at baseline and 12 months following PAE was 13.8 and 13.9, respectively. A total of 55 out of 478 (11.5%) had ≥ 1 adverse event (AE), with 10 (2.1%) experiencing a serious AE. The most common AE was self-limiting irritative symptoms (21.5%; 103/478) which included urinary tract infection (UTI) and hematuria. The authors noted that 16 (3.3%) were re-embolized within 24-months, 32 (6.7%) underwent surgery or another minimally invasive procedure and approximately one-third of participants in both cohorts continued to use medications to manage their BPH (31%) following PAE. Limitations included no control group, missing outcome data due to patients lost to follow-up (missed appointments), and lack of long-term follow-up.

Section Summary: Prostatic Arterial Embolization

Based on the peer reviewed medical literature that includes systematic reviews, RCTs and observational study the current evidence is insufficient regarding the use PAE for the treatment of LUTS secondary to BPH due to a limited comparison with other minimally invasive therapies, the current evidence has found PAE only compared to surgical procedure TURP. While PAE was found to provide short-term benefits regarding reduced blood loss and less urinary catheterizations; TURP was found to provide greater long-term benefits to include better control of urinary symptoms and reduction of prostate size. Compared to TURP PAE was considered reasonably safe, however, the evidence is currently insufficient evaluating the safety of PAE compared to other minimally invasive procedure such as laser enucleation and prostate urethral lift (PUL). Also, patient selection criteria for PAE have not been established. Additional RCTs with > 2 years of follow-up are needed to evaluate the long-term efficacy and safety of PAE to other minimally invasive therapies for the treatment of BPH.

Transrectal Thermal Therapy

Transrectal thermal therapy administers thermal therapy under transrectal ultrasound guidance.

Section Summary: Transrectal Thermal Therapy

There are scarce data in the published peer-reviewed scientific evidence to determine the safety and efficacy of thermal therapy via the rectum as a treatment option for BPH. At this time the role of this therapy has not yet been established.

Transperineal Laser Ablation (TPLA)

Transperineal laser ablation (TPLA) is proposed as a minimally invasive procedure and an alternative to TURP for the treatment of LUTS secondary to BPH. The procedure utilizes optical fibers that deliver laser energy, causing thermal destruction and a reduction of prostate volume. The SoracteLite system is an example of a device that delivers transperineal laser ablation and utilizes a dedicated transrectal ultrasound probe with planning software that displays the estimated ablation area on the ultrasound screen to facilitate insertion. The manufacturer reports the device having the advantages of preservation of healthy tissue and organ function, rapid recovery time, no need for general anesthesia, and little to no post-treatment pain.

Systematic Review

In 2025, Alberti et al conducted a systematic review investigating the efficacy and safety of transperineal laser ablation (TPLA) as a minimally invasive treatment option in men with lower urinary tract symptoms (LUTS) due to benign prostatic hypertrophy (BPH). Reviewers searched PubMed, Embase and Cochrane Central database and identified 17 studies (2 RCTs comparing TPLA with TURP [Bertolo 2023 and Canat 2023], 11 prospective non-randomized single-center studies [Biano 2024, Patelli 2024, LoRe 2024, Minafra 2023, Lagana 2023, Destefanis 2023, Sessa 2023, Manenti 2021, Fergo 2021, DeRienzo 2021, Patelli 2017], 1 prospective non-randomized multi-center study [von Kollenburg 2024], 2 retrospective single-center studies [one comparing TPLA with Prostatic Artery Embolization [PAE] Cai 2023, Polverino 2023] and 1 retrospective multi-center study [Pacella 2020]) involving 702 patients. All TPLA procedures performed used the EchoLaser™ System (SoracteLite™). The pooled analysis found clinically meaningful improvement in urinary flow and voiding based on outcomes related to Qmax 6.02 mL/s (95% CI: 4.73–7.30), with a concomitant reduction in post void residual (PVD) 60.18 mL (95% CI: –81.19 to –39.16), and a decrease in International Prostate Symptom Score (IPSS) score 11.99 points (95% CI: –13.60 to

–10.38) with a median follow-up ≤ 12 months. No major adverse events were reported. Low grade adverse events included transient dysuria, hematuria, catheter displacement/malfunction, urinary tract infection and acute urinary retention. Limitations included small sample size, lack of long-term follow up and study design which included mainly retrospective or prospective single-center observations studies. Also, there is no consensus on which patients would benefit most from this procedure.

Section Summary: Transperineal Laser Ablation

In the systematic review by Alberti et al (2025) the current evidence includes RCTs, prospective and retrospective studies to evaluate the safety and efficacy of TPLA as a MIST option for BPH. While the current evidence may show promising results in these studies a higher level of larger comparative RCTs to standard endoscopic techniques and other MISTs is needed to verify its efficacy in relieving obstructive symptoms and preserving sexual function.

Transurethral Needle Ablation (TUNA)

Based on review of the current peer reviewed medical literature, the use of transurethral needle ablation (TUNA) for the treatment of symptomatic BPH has a diminished role in the treatment of BPH due to its decreasing clinical relevance and the safety of new therapies. This procedure is currently not recommended, see [Practice Guideline and Position Statements](#).

Transurethral Ultrasound-Guided Laser Incision of the Prostate (TULIP)

Transurethral ultrasound-guided laser incision of the prostate (TULIP) is a procedure that is similar to transurethral incision of the prostate except that cuts are made with a laser. Laser energy is delivered under ultrasound guidance, producing necrosis. TULIP is a difficult procedure with a very high incidence of incontinence, a delayed onset of improvement, and no ability to obtain tissue for histological examination. TULIP is rarely used by urologists because it has been surpassed by instruments that are easier to use.

There are scarce data in the published, peer-reviewed scientific literature regarding the effectiveness of TULIP and the role of this therapy in the treatment of BPH has not yet been established.

Section Summary: Transurethral Ultrasound-Guided Laser Incision of the Prostate (TULIP)

Based on review of the current peer reviewed medical literature TULIP is rarely used by urologists because it has been surpassed by instruments that are easier to use and there is limited evidence regarding the effectiveness of TULIP and the role of this therapy in the treatment of BPH has not yet been established.

Water-Induced Thermotherapy (WIT)

Water-induced thermotherapy (WIT) (Thermoflex System) is a minimally invasive therapy that uses hot water circulating through a closed-loop urethral balloon catheter to deliver heat energy to prostate tissue and thereby shrink the prostate and treat symptoms of BPH. It is generally considered only for individuals who cannot undergo TURP or who require less invasive treatments.

There are scarce data in randomized controlled clinical trials or comparative studies regarding outcomes of WIT as a treatment for BPH. Minardi et al. (2004) reported that WIT resulted in a reduction of prostatic

volume of 5.2% compared with a decrease of 48.4% when transurethral resection of the prostate (TURP) was performed. The urine flow rate increased more after TURP (75.3%) than after WIT (16.7%). Residual prostate volume decreased more after TURP (89.8%) than after WIT (25.2%), an increase of maximum flow rate of 16.7% and a decrease of residual volume of 25.2%. The relief of bladder outlet obstruction was indicated by the decrease of detrusor pressure at maximum flow rate in comparison to baseline values; decreases of 27.5% were noted for WIT compared with decreases of 48% for transurethral resection of the prostate (TURP).

Section Summary: Water-Induced Thermotherapy (WIT)

Currently there is insufficient evidence in the peer-reviewed scientific evidence to determine the safety and effectiveness of WIT for the treatment of BPH. Additionally, there is insufficient direct comparison of WIT to other treatment options for BPH; optimal protocols have not been established and long-term information regarding duration of treatment effect or adverse effects is lacking.

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 (AUA)

In 2021, the American Urological Association updated their guideline regarding management of lower urinary tract symptoms attributed to benign prostatic hyperplasia (BPH) which includes the following guideline statements:

Surgical Therapy

Procedure/Patient Population	Recommendation
Transurethral Resection of Prostate (TURP)	"TURP should be offered as a treatment option for patients with LUTS/BPH. (Moderate Recommendation; Evidence Level: Grade B)."
Simple Prostatectomy	"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)."

Procedure/Patient Population	Recommendation
Transurethral Incision of the Prostate (TUIP)	“TUIP should be offered as an option for patients with prostates ≤ 30 cc for the surgical treatment of LUTS/BPH. (Moderate Recommendation; Evidence Level: Grade B).”
Transurethral Vaporization of the Prostate (TUVAP)	“Bipolar TUVAP may be offered as an option to patients for the treatment of LUTS/BPH. (Conditional Recommendation; Evidence Level: Grade B).”
Photoselective Vaporization of the Prostate (PVP)	“PVP should be offered as an option using 120W or 180W platforms for the treatment of LUTS/BPH. (Moderate Recommendation; Evidence Level: Grade B).”
Transurethral Microwave Therapy (TUMT)	“TUMT may be offered as a treatment option to patients with LUTS/BPH. (Conditional Recommendation; Evidence Level: Grade C).”
Water Vapor Thermal Therapy (WVTT)	“WVTT should be considered as a treatment option for patients with LUTS/BPH provided prostate volume 30-80cc. (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).”
Transurethral Needle Ablation (TUNA)	“TUNA is not recommended for the treatment of LUTS/BPH. (Expert Opinion).”
Laser Enucleation	“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).”
Robotic Waterjet Treatment (RWT)	“Robotic waterjet treatment (RWT) may be offered as a treatment option to patients with LUTS/BPH provided prostate volume 30-80cc. (Conditional Recommendation; Evidence Level: Grade C).”
Prostate Artery Embolization (PAE)	“PAE for the routine treatment of LUTS/BPH is not supported by current data, and benefit over risk remains unclear; therefore, PAE is not recommended outside the context of clinical trials. (Expert Opinion).”
Medically Complicated Patients	“HoLEP, PVP, and ThuLEP should be considered as treatment options in patients who are at higher risk of bleeding. (Expert Opinion).”

In 2023, The AUA amended their guidelines regarding the management of lower urinary tract symptoms attributed to benign prostatic hyperplasia (BPH) which included the following:

“The Panel recognizes there are some legacy technologies that have been historically used and are currently FDA approved but have very limited new 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 TUMT and TUNA as 2 of these legacy technologies; therefore, guideline statement referencing these legacy technologies have been removed.”

Procedure	Recommendation
Photoselective Vaporization of the Prostate (PVP)	PVP should be offered as an option using 120W or 180W platforms for the treatment of LUTS/BPH. (Moderate Recommendation; Evidence Level: Grade B.)
Water Vapor Thermal Therapy (WVTT)	“WVTT should be considered as a treatment option for patients with LUTS/BPH provided prostate volume 30-80g. (Moderate Recommendation; Evidence Level: Grade C).”
Laser Enucleation	“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 of options for the treatment of LUTS/BPH. (Moderate Recommendation; Evidence Level: Grade B).”
Prostate Artery Embolization	“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 s (Conditional Recommendation: Evidence Level: Grade C).” “The Panel was unable to find substantial evidence to recommend PAE over more widely available minimally invasive surgical therapies (MISTs) 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. The Panel recommends continued investigation of PAE through trials involve multi-disciplinary teams of urologists and radiologists focused on further defining specific indications, including but not limited to gross hematuria recalcitrant to other therapies.”

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review can be located at clinicaltrials.gov.

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CODES

To report provider services, use appropriate CPT codes, HCPCS codes, Revenue codes, and/or ICD diagnosis codes.

Codes	Number	Description
CPT		

	37242	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural road mapping, and imaging guidance necessary to complete the intervention; arterial, other than hemorrhage or tumor (when specified as prostate arterial embolization)
	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 [when specified as prostatic arterial embolization]
	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
	52450	Transurethral incision of the prostate
	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)
	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) [HoLRP]
	53850	Transurethral destruction of prostate tissue; by microwave thermotherapy [TUMT]
	53852	Transurethral destruction of prostate tissue; by radiofrequency thermotherapy
	53855	Insertion of temporary prostatic urethral stent, including urethral measurement
	55873	Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring)
	55880	Ablation of malignant prostate tissue, transrectal, with high-intensity focused ultrasound (HIFU) including ultrasound guidance
	53899	Unlisted procedure, urinary system

	55899	Unlisted procedure, male genital system
	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
	0950T	Ablation of benign prostate tissue, transrectal, with high intensity-focused ultrasound (HIFU), including ultrasound guidance (may be utilized for SonaBlate)
HCPCS		
	None	
Type of Service	Surgery	
Place of Service	Inpatient/Outpatient/Office	

POLICY HISTORY

Date	Action	Action
October 2025	Annual Review	Policy Revised
October 2024	Annual Review	Policy Revised
October 2023	Annual Review	Policy Revised – content moved from retired policy “Treatments of Benign Prostatic Hyperplasia (BPH)”
February 2023	Annual Review	Policy Revised
September 2022	Interim Review	Policy Revised
February 2021	Annual Review	Policy Revised

Date	Action	Action
July 2020	Interim Review	Policy Revised
February 2020	Annual Review	Policy Revised
February 2019	Annual Review	Policy Revised
February 2018	Annual Review	Policy Revised
September 2017	Interim Review	Policy Revised
June 2017	Annual Review	Policy Revised
June 2016	Annual Review	Policy Revised
July 2015		New Medical Policy

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
PO Box 9232
Des Moines, IA 50306-9232

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