Prostate Surgeries and Interventions

Policy Number: 2026T0618P
Effective Date: June 1, 2026

➲ Instructions for Use

Table of Contents **Page**

Community Plan Policy

- Prostate Surgeries and Interventions

Application

UnitedHealthcare Commercial

This Medical Policy applies to UnitedHealthcare Commercial benefit plans.

UnitedHealthcare Individual Exchange

This Medical Policy applies to Individual Exchange benefit plans.

Coverage Rationale

Transurethral Ablation

Transurethral ablation of the prostate is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Prostatectomy, Transurethral Ablation.

Click here to view the InterQual® criteria.

Transurethral ablation of the prostate is unproven and not medically necessary for all other indications due to insufficient evidence of safety and/or efficacy.

Cryoablation

Cryoablation of the prostate is proven and medically necessary for recurrent prostate cancer diagnosed by biopsy. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Cryoablation, Prostate.

Click here to view the InterQual® criteria.

Cryoablation of the prostate is unproven and not medically necessary for initial treatment of prostate cancer and for all other indications due to insufficient evidence of safety and/or efficacy.

Prostatic Urethral Lift

Prostatic urethral lift is proven and medically necessary for treating urinary symptoms caused by benign prostatic hyperplasia (BPH) when performed according to the following U.S. Food and Drug Administration–labeled indications, contraindications, warnings, and precautions:

- Treating symptoms due to urinary outflow obstruction secondary to BPH, including lateral and median lobe hyperplasia,* in men 45 years of age or older; and
- The following are not present:
  - Prostate volume of > 100 cc
  - A urinary tract infection
  - Urethra conditions that may prevent insertion of delivery system into the bladder
  - Urinary incontinence due to an incompetent sphincter
  - Current gross hematuria

*__Note__: Can be either lateral or median lobe hyperplasia

Prostatic urethral lift is unproven and not medically necessary for all other indications due to insufficient evidence of safety and/or efficacy.

High-Energy Water Vapor Thermotherapy

High-energy water vapor thermotherapy for the treatment of BPH is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Prostatectomy, Transurethral Ablation.

Click here to view the InterQual® criteria.

High-energy water vapor thermotherapy for the treatment of malignant prostate tissue and all other indications is unproven and not medically necessary due to insufficient evidence of safety and/or efficacy.

Transurethral Water Jet Ablation

Transurethral water jet ablation of the prostate is proven and medically necessary for the resection and removal of prostate tissue for the treatment of lower urinary tract symptoms due to BPH.

Transurethral water jet ablation for the treatment of prostate cancer (in individuals who do not meet the criteria above) and all other indications is unproven and not medically necessary due to insufficient evidence of safety and/or efficacy.

Prostate Artery Embolization

Prostate artery embolization is proven and medically necessary for individuals with any of the following:

- Persistent gross hematuria originating from the prostate
- Lower urinary tract symptoms attributable to BPH, as confirmed by a board-certified urologist, with failure of conservative therapy (α-blockers and/or 5-α reductase inhibitors) and any of the following:
  - Significant comorbidities (e.g., American Society of Anesthesiologists Physical Status Classification of class III or higher)
  - Presence of coagulopathy
  - Inability to stop anticoagulation or platelet therapy
  - A prostate volume of > 80 g confirmed by imaging (transrectal ultrasound, magnetic resonance imaging, or computed tomography)

Prostate artery embolization is unproven and not medically necessary for all other indications due to insufficient evidence of safety and/or efficacy.

Other Procedures

The following procedures are unproven and not medically necessary due to insufficient evidence of safety and/or efficacy:

- Transperineal focal laser ablation
- Insertion of a temporary prostatic urethral stent
- Transperineal laser ablation (TPLA)
- Ablation of malignant prostate tissue by magnetic field induction

- Transurethral drug coated balloon dilation
- Transurethral thermal ultrasound ablation (TULSA)
- Irreversible electroporation ablation
- Autologous (e.g., sural) or allogeneic nerve grafts to restore erectile function during or after radical prostatectomy

Medical Records Documentation Used for Reviews

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested; refer to the guidelines titled Medical Records Documentation Used for Reviews.

Definitions

American Society of Anesthesiologists (ASA) Physical Status Classification System: A tool developed over 60 years ago by the ASA to assess and communicate a patient's preanesthesia medical comorbidities. The classification system alone does not predict the perioperative risks, but when it is used with other factors (e.g., type of surgery, frailty, level of deconditioning), it can be helpful in predicting perioperative risks. Classification is as follows:

- ASA I: A normal healthy patient
- ASA II: A patient with mild systemic disease
- ASA III: A patient with severe systemic disease
- ASA VI: A patient with severe systemic disease that is a constant threat to life
- ASA V: A moribund patient who is not expected to survive without the operation
- ASA VI: A declared brain-dead patient whose organs are being removed for donor purposes

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
0582T	Transurethral ablation of malignant prostate tissue by high-energy water vapor thermotherapy, including intraoperative imaging and needle guidance
0655T	Transperineal focal laser ablation of malignant prostate tissue, including transrectal imaging guidance, with MR-fused images or other enhanced ultrasound
0714T	Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance; prostate volume less than 50mL
0738T	Treatment planning for magnetic field induction ablation of malignant prostate tissue, using data from previously performed magnetic resonance imaging (MRI) examination
0739T	Ablation of malignant prostate tissue by magnetic field induction, including all intraprocedural, transperineal needle/catheter placement for nanoparticle installation and intraprocedural temperature monitoring, thermal dosimetry, bladder irrigation, and magnetic field nanoparticle activation
0867T	Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance; prostate volume greater or equal to 50mL
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 performed on prostate tissue)
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
52441	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant

CPT Code	Description
52442	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; each additional permanent adjustable transprostatic implant (List separately in addition to code for primary procedure)
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
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
53850	Transurethral destruction of prostate tissue; by microwave thermotherapy
53852	Transurethral destruction of prostate tissue; by radiofrequency thermotherapy
53854	Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy
53855	Insertion of a temporary prostatic urethral stent, including urethral measurement
53865	Cystourethroscopy with insertion of temporary device for ischemic remodeling (i.e., pressure necrosis) of bladder neck and prostate
53866	Catheterization with removal of temporary device for ischemic remodeling (i.e., pressure necrosis) of bladder neck and prostate
55873	Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring)
55877	Ablation, irreversible electroporation, prostate, 1 or more tumors, including imaging guidance, percutaneous
55881	Ablation of prostate tissue, transurethral, using thermal ultrasound, including magnetic resonance imaging guidance for, and monitoring of, tissue ablation;
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
55899	Unlisted procedure, male genital system
64999	Unlisted procedure, nervous system

Description of Services

Benign prostatic hyperplasia (BPH) is the most common prostate problem for men over 50, with occurrence and symptoms increasing with age. As the prostate enlarges, it presses against the urethra, which results in the thickening of the bladder wall. This can result in urinary retention, trouble starting urination, a week flow, urgency, and needing to push or strain to urinate. Treatment may not be needed for a mildly enlarged prostate unless symptoms are bothersome and affecting quality of life. If needed, treatment for mildly enlarged prostate include lifestyle modifications and medications. When these are ineffective, there are a number of minimally invasive procedures available to destroy prostate tissue or widen the urethra. These treatments can relieve symptoms while minimizing risks of complications of surgical treatments.

Cryoablation, also called cryosurgery or cryotherapy, is a procedure in which transrectal ultrasound is used to guide thin, hollow probes into the perineum. Very cold gas is passed through the probes to freeze and destroy prostate tissue (American Cancer Society, 2023).

The Rezūm™ System uses thermal water vapor to reduce prostate volume that is associated with BPH, including hyperplasia of the central zone and/or a middle lobe (McVary et al., 2021). Another approach, the AquaBeam® Robotic System, uses a heat-free water jet for the ablation of benign prostate tissue.

Transperineal laser ablation is a minimally invasive procedure that uses heat from a low-powered laser to ablate prostate tissue to treat BPH. It is delivered via an optical fiber inserted through the individual's perineal skin and into the prostate using transrectal ultrasound guidance.

Transperineal focal laser ablation (also known as laser interstitial therapy or laser interstitial photocoagulation) is used to treat prostate cancer. Standard treatments for prostate cancer such as surgery and radiation involve the whole gland, even if the tumor is small and localized. These treatment modalities are associated with significant urinary and sexual dysfunction. Focal laser ablation has been proposed as an alternative, as it allows the treatment of only the tumor, sparing the rest of the gland.

In the prostatic urethral lift procedure, permanent UroLift® implants are placed to hold open the lateral and median lobes of the prostate to reduce urinary obstruction (Roerborn et al., 2017).

Prostate artery embolization is the injection of microspheres into the prostatic arteries occluding the vessels, which results in the gradual shrinking of the prostate tissue, thereby widening the urethra and alleviating urinary difficulties.

The ablation of malignant prostate tissue by magnetic field induction involves the intratumoral administration of magnetic nanoparticles, which produce heat in the presence of an alternating magnetic field, resulting in tissue death of the tumor. It is generally used in conjunction with radiation therapy (Albarqi et al., 2020).

A transurethral drug-coated balloon dilation is a novel treatment for BPH and involves a dual mechanism using an antiproliferative agent coated (paclitaxel) dilation system. It is intended to maintain luminal patency of the prostatic urethra after dilation (Kaplan et al., 2023).

Transurethral ultrasound ablation is a novel focal approach to treating localized prostate cancer; a rotating ultrasound probe is placed in the prostatic urethra to apply heat to ablate the prostate tissue. Real-time magnetic resonance imaging–thermometry assures monitoring of heat development during the procedure (Peters et al., 2023).

Irreversible electroporation for prostate cancer is a novel use of the NanoKnife® System, which has emerged as a minimally invasive treatment for prostate cancer that induces cell death via very short but strong pulsed electric fields.

Erectile dysfunction is a common problem after radical prostatectomy (RP). In particular, spontaneous erections are absent in those who have bilateral resection of the neurovascular bundles as part of the RP procedure for treating localized prostate cancer. A technique called nerve-sparing surgery has been developed to prevent damage to these nerves; however, this technique is not possible for some individuals.

Nerve grafting to replace resected cavernous nerves during radical retropubic prostatectomy has been proposed as a technique to increase the likelihood of restoring spontaneous erectile function. During the procedure, a donor nerve (e.g., sural nerve, genitofemoral nerve) is harvested from the person and joined to the distal and proximal ends of the resected cavernous nerve. Grafting may be performed on one or both resected cavernous nerves. The sural nerve (a nerve traveling along the short saphenous vein in the lower leg) is the most common donor nerve used in the nerve grafting procedure during RP. The nerve is considered expendable and has been commonly used in other nerve grafting procedures for repairing injured peripheral nerves. During the sural nerve grafting procedure, a portion of the nerve is harvested from one leg of the individual and grafted to the resected cavernous nerve.

Clinical Evidence

Cryoablation

Chin et al. (2022) conducted a systematic review of the oncological and survival outcomes of cryotherapy for primary and recurrent prostate cancer. Complications and functional outcomes were also assessed. The heterogeneity among the studies made a meta-analysis impossible. Overall, 26 studies were included, with single-arm case series and double-arm retrospective studies comprising 11,228 individuals. Eleven studies were in individuals receiving cryotherapy for recurrent cancer, and 15 were for the primary treatment of newly diagnosed cancer. In the 11 primary treatment studies, the results of 10 showed that disease-specific survival ranged from 90.5% to 100%. Five reported overall survival rates of 61.3% to 98.7%. Two studies showed biochemical-free survival of 53% to 69%. Six studies reported prostate-specific antigen (PSA) nadir levels that ranged from 0.1 to 2.63 ng/mL, and only one reported a PSA decrease of 2 ng/mL. Seven studies assessed recurrence rate using the American Society for Therapeutic Radiology and Oncology Phoenix definition, whereas two studies reviewed the rate of positive postprocedural prostate biopsy. The recurrence rates ranged from 15.4% to 40.3% and 18% to 62%, respectively. The secondary outcomes for primary treatment were inconsistently reported and included urinary incontinence and retention, erectile dysfunction, urethral rectal fistulas, bladder neck stricture/stenosis, infections, hematuria, and hematoma. Among the studies that focused on salvage therapy, for oncological outcomes, six studies reported a cancer-specific survival rate of 65.5% to 100.0%, two studies showed a range of biochemical-free survival from 48.1% to 58.1%, and one study reported an androgen deprivation therapy–free

survival rate of 71.3%. Three studies described an overall survival rate of 92.0% to 99.1%, and two studies reported a median survival rate of 11.8 to 12.3 years. In five studies, the posttherapy PSA nadir level ranged from 0.01 to 2.0 ng/mL. All studies defined biochemical recurrence using the Phoenix definition and reported a range of this recurrence of 13 to 74 months. The secondary outcomes for treating recurrent cancer were also inconsistently reported and included urinary incontinence and retention, erectile dysfunction, urethral rectal fistulas, bladder neck stricture, infections, hematuria, and pelvic perineal pain. The authors concluded that the biochemical and overall survival rates were similar between cryotherapy for primary and recurrent treatment of prostate cancer, but inconsistency in results reporting requires interpreting the results with caution. This review is limited by the heterogeneity of the study design and outcomes reporting. Additional high-quality research is needed.

In a systematic review by Hopstaken et al. (2022), the authors evaluated the effectiveness of focal therapy in individuals with localized prostate cancer. PubMed, Embase, and the Cochrane Library were searched for studies between October 2015 and December 31, 2020. Overall, 72 studies were found, which included 27 studies on high-intensity focused ultrasound (HIFU); nine on irreversible electroporation (IRE); 11 on cryoablation; eight on focal laser ablation and focal brachytherapy; seven on photodynamic therapy; two on radiofrequency ablation; and one on prostatic artery embolization (PAE). Of the 11 studies on cryoablation, six were retrospective studies, one of which compared HIFU with cryoablation, and five were prospective studies. No randomized controlled trials (RCTs) were identified for cryotherapy. The authors concluded that primary focal therapy has potential but continues to remain in its early stages when used for localized prostate cancer. While evidence shows improvement in functional outcomes and minimal adverse effects, additional research is needed to show this therapy's oncological effectiveness. For cryotherapy, the findings are limited by the observational nature of the studies and lack of comparison groups for many of the included studies.

In a Cochrane review, Jung et al. (2018) evaluated the evidence comparing cryotherapy with standard treatment options for the primary treatment of localized or locally advanced prostate cancer. A search was conducted using multiple databases (CENTRAL, MEDLINE, and Embase), clinical trial registries, and a grey literature repository (Grey Literature Report). The search resulted in two RCTs, which included 307 men who were randomized into either a group that received cryotherapy or radiation. The authors found uncertainty regarding the effects of freezing the prostate when compared with radiation treatment. The evidence was of low quality and validated by study limitations, which included selection bias, lack of blinding, violation of inclusion criteria, and inadequate trial completion; further research is needed to validate the findings.

Prostatic Urethral Lift

A 2020 Hayes Health Technology Assessment (updated in 2023) regarding the UroLift System for treating symptoms associated with benign prostatic hyperplasia (BPH) stated that a fair- to low-quality body of noncomparative evidence suggests that prostatic urethral lift (PUL) with the UroLift System may improve lower urinary tract symptoms (LUTSs) associated with BPH for up to 5 years and is not associated with negative sexual adverse events. Substantial uncertainty remains due to the limited comparative evidence base that trended toward favoring transurethral resection of the prostate (TURP) and limited long-term evidence regarding the durability and safety of this device.

In 2017, Roehrborn et al. published 5-year outcomes of the prospective, multicenter, randomized, blinded, sham control trial of PUL in participants with bothersome LUTSs due to BPH. In this 19-center study, 206 participants who were aged ≥ 50 years with an International Prostate Symptom Score (IPSS) of > 12, peak flow rate (Qmax) of ≤ 12 mL/s, and prostate volume of 30 cc to 80 cc were randomized 2:1 to the PUL procedure or blinded sham control. IPSS improvement after PUL was 88% greater than that with sham at 3 months. LUTSs and quality of life (QOL) were significantly improved by 2 weeks, with return to preoperative physical activity within 8.6 days. Improvement in the IPSS, QOL, BPH Impact Index (BPHII), and maximum flow rate (Qmax) were durable through 5 years, with improvements of 36%, 50%, 52%, and 44%, respectively. Symptom improvement was commensurate with participant satisfaction. The authors concluded that PUL offers a durable, minimally invasive option in the treatment of LUTSs due to BPH.

Two-year outcomes were reported by Gratzke et al. (2017) for the BPH6 prospective, multicenter, nonblinded, randomized study (n = 80), which compared PUL with TURP. The inclusion criteria were participants who were aged ≥ 50 years and candidates for TURP, with an IPSS of > 12, maximum urinary flow rate (Qmax) of ≤ 15 mL/s, and prostate volume of ≤ 60 cc on ultrasonography. Parallel 1:1 randomization was performed using permuted blocks of random sizes, stratified by study site. Participants were followed up with visits at 2 weeks, 1, 3, and 6 months, and 1 and 2 years. Significant improvements in the IPSS, IPSS QOL, BPHII, and Qmax were observed in both arms through the 2-year follow-up. IPSS change with TURP was superior to that with PUL at 1 and 2 years, and TURP was superior with regard to Qmax at all time points. Health-related QOL and BPHII improvements were not statistically different. Quality of recovery, as defined by at least a score of 70 on the Quality of Recovery Visual Analog Scale (0-100 scale), was superior for PUL compared with TURP, with 82% of participants in the PUL arm achieving the recovery end point by 1 month compared with 53% of participants in the TURP arm (p = 0.008). The results demonstrate that both the PUL and TURP procedures

offered significant improvement in symptoms, Qmax, and health-related QOL. The modest participant number may not have provided sufficient statistical power to detect differences in some of the secondary outcome variables.

Transurethral Water Jet Ablation

A review of the literature did not find any studies regarding transurethral water jet ablation for treating prostate cancer.

In a multicenter double-blinded RCT, Gilling et al. (2022; included in Hayes Technology Assessment and ECRI Clinical Evidence Assessment) compared the safety and efficacy of aquablation with those of TURP, which is the gold standard for BPH. Overall, 181 participants who were aged 45 to 80 years with BPH were randomized into either receiving aquablation or into the control group (TURP). The aquablation was performed using the AquaBeam Robotic System. The participants were followed up for 5 years, and the staff performing the assessments were blinded for 3 years; years 4 and 5 occurred during the COVID-19 pandemic. The primary efficacy end point was the change in the IPSS from baseline to 6 months and was successfully achieved; at 6 months, the aquablation group showed slightly better numbers, with an IPSS decrease of 16.9 points from baseline, whereas the TURP group had a decrease of 15.1 points. At 5 years, the median IPSS score was 5.5 in the aquablation group and 6 in the TURP group. The Male Sexual Health Questionnaire Ejaculatory Function (MSHQ-EjD) Short Form score averaged 2.7 points lower (or worse) in the TURP group compared with the aquablation group. After 5 years, QOL was no different between the two groups, but 12.3% of the TURP group needed additional BPH therapy, while only 6% of the aquablation participants did. The authors found that the health outcomes from aquablation therapy outweigh those when compared with TURP, and at 5 years, uroflow improvement continues to show durability and consistency. Limitations include the loss to follow-up rate at years 4 and 5 and funding of the study that solely came from the device manufacturer.

Elterman et al. (2021) conducted a meta-analysis of individual patient data from individuals undergoing aquablation treatment for BPH from four selected prospective, global clinical trials: WATER, WATER II, FRANCAIS WATER, and OPEN WATER. Overall, 425 men with BPH were evaluated, with a 1-year follow-up. Items of focus included symptom scores; components of the IPSS; and uroflow and incontinence. In each study, individuals were evaluated using transrectal ultrasound (TRUS), serum PSA, uroflow measures, and completion of the IPSS18 and Incontinence Severity Index (ISI). The authors found that IPSS scores improved significantly in all studies, and at 1 year, an improvement of 16 points from baseline was noted. This study was a meta-analysis of a selected study and was not based on a systematic review of the literature; further limitations include the lack of comparison group, lack of long-term efficacy, and variation in the population of individuals.

In a 2021 Hayes Technology Assessment, updated in 2024, regarding aquablation for treating BPH, it was concluded that a low-quality body of evidence suggests that it may improve LUTSs that are associated with BPH in the short to intermediate term, without impacting sexual function and without serious safety concerns. However, substantial uncertainty remains due to the scarcity of evidence comparing aquablation to TURP, and long-term evidence is limited. Furthermore, clarity is lacking as to which population of individuals is likely to benefit the most from aquablation therapy.

Gilling et al. (2020) reported the results in participants from the WATER I clinical trial to report 3-year outcomes for aquablation compared with TURP for the treatment of LUTSs related to BPH. Assessments included the IPSS, the MSHQ-EjD, the International Index of Erectile Function (IIEF), and uroflow. Over 3 years of treatment, improvements in IPSS scores were statistically similar across groups. Mean 3-year improvements were 14.4 and 13.9 points in the aquablation and TURP groups, respectively (difference of 0.6 points; 95% CI, -3.3 to 2.2; $p = 0.6848$). Similarly, 3-year improvements in Qmax were 11.6 and 8.2 cc/sec (difference of 3.3; 95% CI -0.5 to 7.1 cc/sec; $p = 0.0848$). At 3 years, PSA was reduced significantly in both groups by 0.9 and 1.1 ng/mL, respectively; the reduction was similar across groups ($p = 0.6$). There were no surgical retreatments for BPH beyond 20 months for either aquablation or TURP. It was concluded that 3-year BPH symptom reduction and urinary flow rate improvement were similar after TURP and aquablation therapy. No participants required surgical retreatment beyond 20 months post operation. This study is limited by a maximum prostate size of 80 cc and whether the rigor of clinical trial data can be applied in real-world settings. Furthermore, the study may have been too small to detect clinically significant differences at 3 years, as it was powered for noninferiority at 6 months.

Desai et al. (2020; included in ECRI Clinical Evidence Assessment) reported the 2-year safety and effectiveness of aquablation in men with larger prostate volumes of 80 to 150 cc in a prospective, multicenter, international case series (WATER II). Participants had a mean prostate volume of 107 cc, and the results showed that the IPSS and IPSS QOL improved from 23.2 to 1.1 and 4.6 to 1.1 from baseline to 2 years, respectively. Maximum urinary flow increased from 8.7 to 18.2 cc/sec. By the end of the 2-year study time frame, all but two of the 74 participants stopped taking α-blockers, and all but 32 stopped taking 5-α reductase inhibitors. During the 2-year study time frame, adverse urological events were low and included two participants with recurrent BPH symptoms that required retreatment with TURP and HoLEP (Holmium Laser Enucleation of the Prostate). The authors concluded that the aquablation procedure is a safe and effective

treatment for men with LUTSs due to BPH with larger prostate volumes and that it has an acceptable safety profile and a low retreatment rate. This trial is limited by a lack of a control group, which prevented direct comparison to other treatments.

Bach et al. (2020) conducted an international, prospective, multicenter, single-arm, open-label clinical trial of the efficacy of the aquablation procedure for the treatment of LUTSs due to BPH in 177 participants who were enrolled at five treatment centers between September 2017 and December 2018. The primary end point was the change in total IPSS from baseline to 3 months. The secondary end points included (1) the proportion of participants who were sexually active at baseline and experienced either ejaculatory or erectile dysfunction at 3 months and (2) change from baseline to 3 months in maximal flow rate (Qmax), PSA level, postvoid residual (PVR), total MSHQ score, and selected IIEF-5 score. The degree of dysuria was collected on a 0 (not at all) to 5 (almost always) scale. The inclusion criteria were a diagnosis of LUTSs due to BPH and a prostate size between 20 and 150 cc. The exclusion criteria included an inability to stop anticoagulants and antiplatelet agents prior to the operation or a bleeding disorder; history of gross hematuria; current use of systemic immune suppressants; contraindication to both general and spinal anesthesia; unwillingness to accept transfusion if required; or any severe illness that could prevent complete follow-up. At baseline and the 3- and 12-month follow-ups, participants completed the IPSS, ISI, Pain Intensity Scale, Quality of Recovery Visual Analog Scale, IIEF-15, MSHQ-EjD, and uroflowmetry and PVR measurements. The results showed that of the original 177 participants who were enrolled and had the procedure completed, by month 12, 30 were lost to follow-up, three voluntarily withdrew, and one died of an unrelated cause. Mean IPSS improved from 21.7 (7.1) at baseline to 7.1 (5.8) at the 3-month follow-up and 6.4 (4.8) at the 12-month follow-up. IPSS QOL scores improved from 4.7 (1.1) at baseline to 1.5 (1.4) at the 3-month follow-up and 1.4 (1.4) at the 12-month follow-up. IPSS storage and voiding scales also improved significantly ($p < 0.0001$) at 3 and 12 months. The maximum urinary flow rate increased from 9.9 (5.3) cc/sec at baseline to 20.3 (11.4) cc/sec at month 3 and 20.8 (11.2) cc/s at month 12. PVR improved from 108 (108) to 47 (77) cc at 3 months and 61 (74) cc at 12 months. Of the 92 men who were sexually active at baseline and 12 months, the MSHQ-EjD score changed by -1 at 3 months and -1.1 points at 12 months. MSHQ bother/satisfaction changed by -0.3 and -0.7 points at 3 and 12 months, respectively. IIEF-15 scores remained stable through month 3. Overall, 141 participants had TRUS at baseline and after 3 months, which showed a decrease in prostate size of 36%. Leakage of urine was reported by 68% of participants at baseline and had reduced to 55% at 12 months, and the ISI improved nonsignificantly. Dysuria of any frequency was reported by 51% at baseline and 29% at the 3-month follow-up, and associated pain decreased from 3.5 to 2.4. General pelvic pain decreased from 1.3 at baseline to 0.4 at the 3-month follow-up. Overall, 82 of the participants were taking medication for BPH prior to the operation, and by month 3, all but eight had discontinued the medication. There were 69 adverse events reported in 56 participants: 33 grade 1 events, 15 grade 2 events, five grade 3a events, and 16 grade 3b events. The authors concluded that aquablation is safe and effective for individuals with LUTSs due to BPH and replicates results that were previously seen in a trial setting. This study is limited by a lack of a concurrent control group and relatively short-term efficacy and follow-up.

A 2019 Cochrane review on aquablation (Hwang et al., included in ECRI Clinical Evidence Assessment) identified only one RCT, which is the Gilling et al. study described below. The authors concluded that based on short-term (up to 12 months) follow-up, the effect of aquablation on urological symptoms is probably similar to that of TURP (moderate-certainty evidence). The effect on QOL may also be similar (low-certainty evidence). There is uncertainty whether individuals undergoing aquablation are at a higher or lower risk for major adverse events (very low-certainty evidence). Aquablation may result in little to no difference in erectile function but may offer a small improvement in preservation of ejaculatory function (both very low-certainty evidence). These conclusions are based on a single study of men with a prostate volume of up to 80 mL in size. Longer-term data and comparisons with other modalities appear critical to a more thorough assessment of the role of aquablation for the treatment of LUTSs in men with BPH.

Gilling et al. (2019; included in the Hayes Health Technology Assessment and ECRI Clinical Evidence Assessment) compared 2-year safety and efficacy outcomes after aquablation or TURP for the treatment of LUTSs related to BPH. A total of 181 individuals with BPH were randomly assigned (2:1 ratio) to either aquablation or TURP. Individuals and follow-up assessors were blinded to treatment. Assessments included the IPSS, the MSHQ, the IIEF, and uroflow. At 2 years, IPSS scores improved by 14.7 points in the aquablation group and 14.9 points in the TURP group ($p = 0.8$; 95% CI, -2.1 to 2.6). Two-year improvements in Qmax were 11.2 and 8.6 cc/s with aquablation and TURP, respectively ($p = 0.2$; 95% CI, -1.3 to 6.4). Sexual function, as assessed by the MSHQ, was stable in the aquablation group and decreased slightly in the TURP group. At 2 years, PSA was reduced in both groups by 0.7 and 1.2 points, respectively; the reduction was similar across groups ($p = 0.2$). Surgical retreatment rates after 12 months for aquablation were 1.7% and 0% for TURP. Over 2 years, surgical BPH retreatment rates were 4.3% and 1.5% ($p = 0.4$), respectively. The authors concluded that the 2-year efficacy outcomes after TURP and aquablation were similar, and the rate of surgical retreatment was low and similar to that for TURP. Aquablation may be an alternative for men who strongly prefer maintenance of ejaculatory function; however, the sample size may have been too small to detect clinically important differences.

Reale et al. (2019; included in Hayes Health Technology Assessment and ECRI Clinical Evidence Assessment) performed a systematic review of case series and comparison studies to evaluate functional outcomes (Qmax, QOL, the IPSS, and PVR), sexual outcomes (erectile dysfunction and anejaculation rate), and adverse events evaluated according to the Clavien-Dindo classification. The functional outcomes, evaluated after water jet dissection, showed improvement with respect to baseline in all the selected articles. In the comparison papers with TURP, aquablation was statistically not inferior regarding functional outcomes. The sexual outcomes highlighted a better ejaculation rate for water jet dissection than TURP. Regarding the adverse events, water jet dissection documented low rates of adverse events, and in comparison studies, these were not statistically superior to those with TURP. Multicenter randomized trials, with larger cohorts and longer follow-up, are still needed.

A study to compare urodynamic outcomes between aquablation vs TURP was performed (Pimentel et al., 2019, included in Hayes Health Technology Assessment and ECRI Clinical Evidence Assessment). Individuals (n = 66) were randomized 2:1 (aquablation:TURP) in the Waterjet Ablation Therapy for Endoscopic Resection of prostate tissue study. Urodynamics were measured at baseline and 6 months. At the mean baseline, pDet@qmax was 71 and 73 cm H20 in the aquablation and TURP groups, respectively. At the 6-month follow-up, pDet@qmax decreased by 35 and 34 cm H20, respectively. A large, negative shift in the Bladder Outlet Obstruction Index was observed, consistent with a large reduction in the proportion of individuals with obstruction at the follow-up compared with baseline (79% to 22% in aquablation and 96% to 22% in TURP). The authors concluded that in this trial, improvements after aquablation in objective measures of bladder outlet obstruction were similar to those observed after TURP.

A 2018 ECRI Clinical Evidence Assessment, updated in 2023, of the AquaBeam Robotic System for treating BPH reported that based on evidence from one RCT and four systematic reviews, aquablation is safe and reduces BPH-related LUTSs for up to 5 years in individuals with prostates between 80 and 150 mL. Systematic reviews reported that aquablation works as well as or better than UroLift, Rēzum, iTind, and PAE, but these comparisons are indirect, and firm conclusions cannot be drawn. Studies also show outcomes that are as good as or better than those with TURP, and fewer individuals required retreatment at the 5-year follow-up. Additional studies are needed that compare AquaBeam with other minimally invasive treatments for LUTSs due to BPH.

Plante et al. (2018; included in Hayes Health Technology Assessment and ECRI Clinical Evidence Assessment) conducted a prespecified, post hoc, exploratory subgroup analysis from a double-blinded, multicenter, prospective RCT that compared TURP using either standard electrocautery vs surgery using robotic water jet (aquablation) to determine whether certain baseline factors predicted more marked responses after aquablation compared with TURP. The primary efficacy end point was the reduction in the IPSS at 6 months. The primary safety end point was the occurrence of Clavien-Dindo persistent grade 1 or grade ≥ 2 surgical complications. For men with larger prostates (50-80 g), the mean IPSS reduction was four points greater after aquablation than after TURP, which was a larger difference than the overall result. The primary safety end point difference was greater in individuals with a large prostate compared with the overall result. Postoperative anejaculation was also less common after aquablation compared with TURP in sexually active individuals with large prostates vs the overall results. An exploratory analysis showed larger IPSS changes after aquablation in individuals with enlarged middle lobes, severe middle lobe obstruction, low baseline maximum urinary flow rate, and elevated PVR urine volume. The authors concluded that in individuals with moderate to severe LUTSs that are attributable to BPH and larger, more complex prostates, aquablation was associated with both superior symptom score improvements and a superior safety profile, with a significantly lower rate of postoperative anejaculation. The authors noted that the standardized, robotically executed, surgical approach with aquablation may overcome the increased outcome variability in more complex anatomy, resulting in superior symptom score reduction. The RCT reported short-term outcomes and included individuals with a prostate size of 30 to 80 cc. Therefore, the results may not be generalizable to all prostate sizes.

Gilling et al. (2017; included in Hayes Health Technology Assessment) performed a prospective, single-arm, multicenter trial at a total of three centers in Australia and New Zealand, with a 1-year follow-up, to establish the safety and effectiveness of aquablation, an image-guided, robotic-assisted, water jet tissue ablation technology, for the treatment of BPH. A total of 21 participants with moderate to severe LUTSs were included in the study, with in-clinic follow-up visits at 1, 3, 6, and 12 months. The visits included a review of adverse events, uroflow measurements, PSA measurement (at 6 and 12 months only), completion of study questionnaires, and (at 6 months only) urodynamics and TRUS. Symptoms related to LUTSs had significantly improved from baseline at 1 month and were sustained through month 12. At 12 months, the mean IPSS score had improved by 16.2 points. The IPSS QOL component improved by 3.3 points. Mean maximum urinary flow improved from 8.7 ml per second at baseline to 18.3 ml per second, and PVR volume improved from 136 to 54 ml. Prostate volume decreased from 57 ml at baseline to 35 ml. The Bladder Outlet Obstruction Index decreased from 48 at baseline to 13 at month 6. Mean serum PSA, which was measured in 20 participants, showed no significant change from 3.15 ng/ml at baseline to 2.56 ng/ml at 12 months. No urinary incontinence developed, and sexual function was preserved post operation. The authors concluded that this study provides early evidence to support the

safety and effectiveness of aquablation for symptomatic BPH by improved symptom scores and other measures of obstruction. The study had a small sample size and lacked a concurrent control group.

High Energy Water Vapor Thermotherapy of Malignant Prostate Tissue

A search of the literature did not identify relevant peer-reviewed, original data publications.

Prostate Artery Embolization

There is insufficient evidence to assess the efficacy of PAE relative to laser enucleation of the prostate or PUL. Additional RCTs, with long-term follow-up, are needed to evaluate the long-term efficacy and safety of PAE relative to TURP and other minimally invasive therapies for BPH, particularly in male persons who are poor candidates for TURP due to frailty or comorbidities. However, PAE may be indicated for some individuals who are not eligible for surgery or who have persistent gross hematuria originating from the prostate.

In 2023 and updated in 2025, Hayes conducted a Health Technology Assessment regarding PAE and compared it to open prostatectomy and minimally invasive procedures for moderate to severe BPH that is refractory to medical treatment. It was concluded that an overall low-quality body of evidence suggests that compared with TURP, PAE provides short-term benefits, including reduced blood loss, less need for urinary catheterization, and shorter hospitalization; however, TURP consistently provides greater long-term benefits. There is insufficient evidence to assess the efficacy of PAE compared with that of laser enucleation of the prostate or PUL. Additional RCTs, with more than 2 years of follow-up, are needed to evaluate the long-term efficacy and safety of PAE relative to TURP and other minimally invasive therapies for BPH, specifically for those who are poor candidates for TURP due to frailty or comorbidities.

In a 2023 systematic review, Veyg et al. compared the 24-month outcomes following PAE for symptomatic BPH in individuals with a prostatic volume of > 80 mL with those in individuals with a volume of < 80 mL. A total of 14 studies, with 2,260 individuals, were included. Ten studies included a prostatic volume of greater than 80 mL, and four included a prostatic volume of less than 80 mL. Prior to the operation, the mean prostatic volume was 110.1 mL, and the mean IPSS, PVR, and Qmax were 22.6, 126.9 mL, and 8.3 mL/s, respectively. The mean preprocedural IIEF-5 score and PSA were 17.5 and 6.3 ng/mL. Most of the studies reported PAE via femoral access and reported successful bilateral embolization using particles ranging from 50 to 500 µm in size. At the 24-month follow-up, the results showed a mean IPSS of 8.4. Other outcomes were not consistently reported among all the studies. Ten studies reported a PVR of 58.5, nine reported a Qmax score of 14.7, and seven reported IIEF-5 scores of 13.1. Overall, 12 studies measured PSA and showed a mean value of 3.6 ng/mL. Both groups experienced similar symptomatic improvement at the 24-month follow-up, with no significant difference in objective measurements of urinary retention and LUTSs. The authors concluded that PAE is a safe and effective treatment for even large-volume prostates, especially in individuals with comorbidities that make them poor surgical candidates. This study is limited by a high level of heterogeneity in outcome reporting, and further research is required to validate these findings.

In 2021, Abt et al. reported the 2-year safety and efficacy outcomes of the open-label, randomized noninferiority trial that they conducted in 2018, for which 12-week outcomes were reported previously. In the 2018 trial (included in the Xiang et al. systematic review), 103 participants aged 40 years or greater with refractory LUTSs secondary to benign prostatic obstruction (BPO) were treated with either PAE using 250- to 400-µm microspheres under local anesthesia or monopolar TURP under spinal or general anesthesia. The IPSS and other participant-reported outcomes, functional measures, prostate volume, and adverse events were evaluated. Changes from baseline to 2 years were tested for differences between the two interventions with standard two-sided tests. For the participants who received PAE, the results showed that the mean reduction in the IPSS was 9.21 points and 12.09 points after TURP (difference of 2.88; 95% CI, 0.04-5.72; p = 0.047). TURP showed superiority for most other participant-reported outcomes as well (except erectile dysfunction), including maximum urinary flow rate, reduction of PVR urine, and reduction of prostate volume. Adverse events were less frequent after PAE than after TURP, but the severity was similar. Overall, 21% of participants who initially received PAE required TURP within 2 years due to unsatisfactory results. The authors concluded that PAE for the treatment of BPH remains investigational due to inferior functional outcomes and a relevant retreatment rate found 2 years after PAE compared with TURP. These disadvantages should be considered for selection of individuals and counseling.

Pisco et al. (2020) conducted a randomized clinical trial to assess the safety and efficacy of PAE vs. those of a sham procedure for BPH-related LUTSs in participants with severe LUTSs refractory to medical management with α-blockers. Following catheterization of a prostatic artery, 80 participants who were ≥ 45 years of age were randomized 1:1 to receive PAE or the sham procedure of no embolization. The primary outcomes were assessed at 6 months and included the change in the IPSS and QOL from baseline. The secondary outcomes included BPHII, IIEF-5, prostate volume, Qmax, post- void residual, and PSA. Study population ages ranged from 48 to 76 years, and both arms had similar baseline characteristics. The results showed that in the PAE group, a change in IPSS score from 25.5 to 8.75 occurred, and the

sham group had a change from 27.5 to 21.9. For the QOL measurement, the sham group had a change from 4.5 to 3.8, and the PAE group went from 4.0 to 1.35. There were clinically and statistically significant changes across secondary outcomes, with no worsening of the IIEF-5 score. Furthermore, in the sham group, 34 participants (91.9%) were still taking medication at the end of the main study compared with only two (5.13%) in the PAE group. Regarding adverse events, 16 occurred in the PAE group, and 17 occurred in the sham group. These included pain, bruising, hematospermia, and hematuria, and three participants experienced inguinal hematoma. Two participants with dysuria and burning urethral pain and one UTI were medically managed. One participant experienced expelled prostate fragments that caused urinary hematuria and was treated with TURP. All others subsided spontaneously. The authors concluded that PAE is a safe and effective treatment for BPH-related LUTSs and offers improvement in subjective and objective symptoms, with no negative impact on sexual function. This study is limited by the short follow-up time and inclusion of only severe LUTSs, with larger prostate sizes making extrapolation for less severe LUTSs or smaller prostates not possible. Future research, with longer follow-up and comparisons to other treatments, is needed to validate these findings. This study is included in the Hayes 2025 Health Technology Assessment.

In 2019, Zumstein et al. performed a systematic review and meta-analysis of clinical trials comparing the efficacy and safety of PAE with those of established surgical therapies. The functional parameters assessed included maximum urinary flow, PVR, and reduction of prostate volume. There were five comparative studies, consisting of 708 individuals, some of which had an unclear risk of bias in selection of individuals, blinding, and incomplete outcome data. Reporting of complications varied widely and was poor in some. The results showed that compared with standard surgical therapies, PAE showed less improvement in the IPSS and was less efficient in all functional parameters assessed. Conversely, self-reported erectile function was better after PAE, and there were significantly fewer adverse events overall. The authors concluded that PAE is safe and effective in the short term, particularly regarding safety and sexual function, but clear disadvantages for all other self-reported and functional outcomes assessed, compared with established surgical therapies, were identified. This suggests that PAE is not as effective as established surgical therapies. The authors recommended performing large-scale RCTs that include longer follow-up as well as defining ideal indications that are mandatory before PAE can be considered as a standard treatment option. (This study is included in the Xiang et al., 2021, systematic review and meta-analysis.)

In a 2019 retrospective study, Tian et al. assessed the safety and efficacy of PAE for treating BPH-induced gross hematuria refractory to medical management for at least 3 months in 20 patients. All patients were not candidates for or refused surgery. Baseline imaging, PSA, prostatic volume, the IPSS, and QOL were recorded. The results showed that gross hematuria was resolved as follows: day 1 in one patient, day 2 in 10 patients, day 3 in four patients, day 4 in three patients, and day 5 in two patients. At the 3-month follow-up, three patients reported recurrent hematuria and underwent TURP, and at 12 months, hematuria had recurred in one of the remaining 17 patients. Regarding the IPSS and QOL, scores were available for 18 of the 20 patients and showed a mean decrease in the IPSS from 21.1 to 9.8 and QOL from 5.1 to 1.3. At 12 months, the scores in 15 patients showed that the IPSS dropped to 8.1 and the mean QOL to 2.1. There were no major complications reported with angiography or embolization, and minor complications included gluteal pain, nausea, and fever in seven patients and resolved with treatment. The authors concluded that PAE is safe and effective and is a reasonable choice of treatment for individuals who are not candidates for surgery or refuse surgery. This study is limited by a retrospective design, lack of comparison, short follow-up period, and small number of patients. Further research is needed to validate these findings.

In a 2018 prospective study, Tapping et al. assessed the effectiveness of PAE for the control of hematuria and BPH with normal upper urinary tracts. Twelve participants were included, and all had imaging and cystoscopy to confirm the prostatic origin of hematuria. Following embolization, the participants were followed up at 3, 12, and 18 months using QOL, the IPSS, the IIEF, and clinical review. The results showed that bilateral PAE was technically successful in all 12 participants. At the 3-month follow-up, all hematuria was resolved. Improvements were seen in IPSS, IIEF, and QOL scores, and there were no adverse events reported (postembolization syndrome, nontarget embolization, or access site complications). The only case of recurrent hematuria was in a participant who was over-anticoagulated, and when that was addressed, the hematuria ceased. The authors concluded that PAE is safe and useful for controlling BPH and hematuria. This study is limited by the lack of a comparison group, small number of participants, and reliance on participants' reporting of no hematuria. This study also had a short follow-up period, and further studies are needed to validate these findings.

Bhatia et al. (2018) conducted a retrospective review to evaluate the safety and efficacy of PAE in 30 catheter-dependent patients with large prostate volumes and high comorbidity scores. All patients presented with urinary retention and underwent PAE following at least two attempts at voiding without catheterization, and all had received prior pharmacological treatment. Those who had neurogenic disorders or less than 3 months of follow-up were excluded. Patients with a baseline PSA of > 4 underwent prostate biopsy to rule out malignancy. Overall, 24 had indwelling catheters, and six were using intermittent catheterization. Patients were assessed at 3, 6, and 12 months. The results

showed that embolization was clinically successful in 26 patients. The mean time to catheter discontinuation was 18 days, and these patients were catheter free at 3 months of follow-up. Additional follow-up in 24 patients at 6 months and 17 patients at 12 months showed that none required reintroduction of catheterization, and the IPSS and QOL improved significantly from baseline. At the 3-month follow-up, 23 patients had discontinued all use of medications. Grade I complications occurred in 12 patients and predominantly consisted of hematuria, and all were resolved with the use of urinary analgesics or antimuscarinic medications. The authors concluded that PAE is a safe and effective treatment for individuals who are not surgical candidates, with clinical benefit lasting at least 12 months. This study is limited by a small number of patients and lack of a control group, and further research is needed to validate these findings before firm recommendations for PAE as a treatment option can be made.

Rampoldi et al. (2017) conducted a prospective case series to assess the technical feasibility, safety, and efficacy of PAE for the treatment of bladder outlet obstruction LUTSs due to BPH managed with indwelling bladder catheterization (IBC) in poor surgical candidates. Overall, 40 participants who were deemed poor candidates for endoscopic or surgical therapy due to at least one severe comorbidity were included. The most common were congestive heart failure, chronic obstructive pulmonary disease, and renal disease. Twelve participants had oncological comorbidities, including multiple myeloma, leukemia, and prior prostate cancer as well as colorectal, lung, skin, and bone cancers. Additionally, four had a pacemaker, and three were on anticoagulation medication that could not be discontinued. In total, 20 participants were not eligible for uroflowmetry due to continued IBC or poor clinical status. Bilateral embolization was achieved in one procedure for 30 participants, and two required a second procedure. Unilateral embolization was performed in eight participants, and the procedure was aborted in two due to hypogastric prostate artery stenosis. The mean follow-up time was 13 months. At the 6-month follow-up, the results showed prostate size and IPSS score reduction. Clavien II complications were reported in nine participants and included UTI and episodes of acute urinary retention requiring temporary indwelling catheter placement. Nine participants experienced postembolization syndrome in the 48 hours following the procedure. The results showed that IBC removal was achieved in 33 participants at follow-up. It was concluded that PAE is a safe and efficacious procedure in individuals who are poor surgical candidates and have no other treatment options.

In a 2016 prospective study, Gabr et al. evaluated the efficacy and safety of PAE in participants with BPH refractory to medication management or who had an indwelling catheter due to urine retention and were at a high risk for surgery and/or anesthesia. Overall, 22 participants, with a mean age of 72 years and mean prostate volume of 77, were included. All were not eligible for standard BPH surgical treatment due to a high surgical risk due to comorbidities. All participants had an American Society of Anesthesiologists score of 3. Preoperative and 1-, 3-, and 9-month posttreatment assessments included the IPSS, the IIEF-5, a physical examination, urinalysis, complete blood cell count, serum creatinine, a coagulation profile, PSA, uroflowmetry, an abdominal ultrasound, and TRUS. The exclusion criteria included participants with an IPSS of < 8; prostate size of < 60 g; suspicion of prostate cancer; ultrasound finding or elevated serum PSA; previous lower urinary tract surgery; history of urethral stricture; bladder stones; neurogenic bladder; large bladder diverticulum; other urethral/bladder abnormalities; and advanced atherosclerosis or tortuosity of the aortic bifurcation, prostate, or internal iliac arteries. Those with a medical condition that contraindicated iodine contrast media were also excluded. The results showed technical success in all 22 participants, and no procedural complications were experienced. In the first month of follow-up, 15 participants developed a UTI, which responded to antibiotics. All participants were able to successfully urinate after catheter removal, and baseline clinical parameters were improved from the first follow-up through 9 months. There was also a significant reduction in PSA level and PVR urine and prostate volumes. The authors concluded that PAE is a safe and effective treatment to relieve BPH-related LUTSs in individuals who are at high risk for surgery and/or anesthesia. This study is limited by a lack of a comparison group, lack of randomization, short follow-up period, and small number of participants. Larger, randomized studies, with longer follow-up times, are needed to validate these findings.

Transperineal Focal Laser Ablation

The quality of the evidence is insufficient to support the efficacy and safety of this technology. Furthermore, the findings for oncological outcomes are conflicting, and studies are limited by short-term follow-up.

In a 2025 systematic review, Poverino et al. assessed the evidence on the functional and oncological outcomes of transperineal focal laser ablation. Ten retrospective, prospective, and prospective randomized studies met the inclusion criteria, with numbers of individuals ranging from seven to 55; individuals were aged 43 to 86 years. All studies had an overall high risk of bias. Biases included the randomization process, deviations from the intended intervention, missing outcome data and outcome measurements, and selection of reported results. While individuals in all the included studies underwent evaluation with multiparametric magnetic resonance imaging (MRI), biopsy techniques differed in approach (transrectal vs. transperineal) and technique (targeted vs. systemic). Gleason scores of treated lesions varied widely, and two studies did not report the score at all. Treatment was performed using various laser systems, and there was significant heterogeneity of the treatment protocols. The results for oncological outcomes showed various rates of

effectiveness on biopsy that ranged from 4% to 57%, and clinically significant cancer was reported in eight studies. Biochemical disease–free survival was not consistently reported, and treatment failure was reported in four studies, but this too was inconsistently defined. Secondary treatments, including retreatment with ablation and radical prostatectomy, were reported in 7% to 30% and were primarily due to residual disease. Complication rates varied, with most being Clavien-Dindo I and II. The results of urinary function were not consistently reported (four of 10 studies); however, those studies that did report these results showed that most individuals had complete continence post treatment. Sexual function outcomes were also not consistently reported, but when they were, there were no significant changes. The authors concluded that transperineal focal laser ablation for prostate cancer is safe and effective, but reliable evidence is limited, and additional high-quality research that includes standardization and comparison to established treatment is needed.

In a 2024 interventional pilot study, Manenti et al. (2024) aimed to evaluate the short- and medium-term (3 years) oncological and functional outcomes of transperineal laser ablation (TPLA) for the treatment of the index lesion in 40 participants who were aged 46 to 86 years; had low- or intermediate-risk prostate cancer, as defined by a Gleason score of < 4 +3; and had a PSA below 20 ng/mL and staging below T2b. Follow-up occurred at 1, 6, 12, 24, and 36 months, with PSA and multiparametric MRI evaluated. At 36 months, the IPSS and IIEF-5 questionnaires were repeated, and a systematic and target MRI/ultrasound fusion–guided prostate biopsy was done. Of the original 40 participants, 15 were lost during follow-up. The results report the data on 20 participants; in five participants, the multiparametric MRI at 12 months showed a focal lesion adjacent to the ablation cavity. These were biopsied and were indicative of residual cancer. Oncological outcomes showed an increase in PSA levels at 1 month (due to destruction of cancer cells), then a significant decline at subsequent follow-up intervals, with a mean reduction of more than 60% at the 36-month follow-up. Functional outcomes showed that the mean IPSS score decreased from 7.35 to 6.70 over the 36-month follow-up ,and erectile function, as measured by the IIEF-5 score, increased from 14.20 to 15.50 during the same follow-up. Both score increases were considered insignificant. Furthermore, with random biopsies throughout the 36-month follow-up, in 10 participants, new foci lesions appeared outside the ablation zone. The authors concluded that focal laser ablation was effective and safe for this group of participants but that further high-quality research, with longer follow-up, is needed to validate the safety and efficacy of TPLA as a treatment option for low- to intermediate-risk prostate cancer.

Iacovelli et al. (2024; included in Poverino et al., 2025) conducted a prospective, single-center, single-arm, interventional pilot study to evaluate the oncological and functional outcomes of TPLA for localized prostate cancer in 24 participants with stage < T2 disease, PSA of < 20 ng/mL, International Society of Urological Pathology (ISUP) grade of ≤ 2, and MRI-fusion biopsy–confirmed disease. Participants with previous pelvic radiation, a history of other genitourinary malignancies, multifocal disease, or a tumor diameter of ≥ 2 cm or who had no MRI data were excluded. Postoperative follow-up visits were conducted at 3, 6, and 12 months, and multiparametric MRI was performed at months 3 and 12. All participants underwent rebiopsy at 12 months. The results showed improvement in IPSS, IPSS QOL, and International Consultation on Incontinence Questionnaire-Short Form scores at 3 months, and erectile and ejaculatory functions showed no significant variation during follow-up. Oncological outcomes showed that at 3 months, there was complete ablation of the index lesions and no new lesions in all participants, which correlated with a significant reduction in PSA values. At 12 months, imaging showed that eight participants had recurrent disease, and following biopsy, seven were confirmed to have recurrent prostate cancer, with three having recurrence of the target lesion. No adverse events or readmission was reported. The authors concluded that TPLA is a safe and effective treatment for individuals with low- or intermediate-risk prostate cancer, despite a lack of proper radiological methods to show the effects of TPLA on prostatic tissue and to detect eventual prostate cancer relapses. This pilot study was limited by the single-arm design, small number of participants, and short follow-up period.

Bates et al. (2021) conducted a systematic review to compare the clinical effectiveness of primary focal ablative therapy with that of standard current treatment options for clinically localized prostate cancer. Four primary studies (one RCT and three retrospective studies), including 3,961 individuals (and 10 eligible systematic reviews were identified), that reported on different types of focal therapy were included. The RCT compared photodynamic therapy with active surveillance, and a retrospective matched-pair study compared focal HIFU with robotic radical prostatectomy. Two retrospective Surveillance, Epidemiology, and End Results–based, propensity-matched cohort studies compared focal laser ablation against radical prostatectomy and external beam radiotherapy (EBRT), reporting significantly worse overall survival with focal laser ablation on adjusted analysis. The authors concluded that overall, the evidence in support of focal therapy as an alternative to either active surveillance or radical interventions for localized prostate cancer was limited. Data regarding the oncological effectiveness were mixed and inconsistent. For focal laser ablation specifically, limited quality data suggest harm compared with alternative, established therapies. Overall, for focal therapy, the vast majority of primary studies were small and uncontrolled; others were comparative studies with serious methodological flaws, with extremely low internal and external validity. Most studies had significant clinical heterogeneity, with poorly defined populations and interventions (e.g., intermingling of whole-gland and focal therapy as a single index intervention); different definitions of retreatments with different intervals; different imaging and follow-up schedules; different comparators; outcome measures

with different definitions of treatment failure measured at different time points; and a lack of long-term data. The overview of systematic reviews confirmed these findings, and none showed high-certainty evidence. The authors concluded that the routine use of focal therapy in clinical practice is currently not recommended and should ideally be restricted to a clinical trial or prospective comparative study involving comprehensive data capture using standardized definitions and appropriate outcome measures.

Valerio et al. (2017) completed a systematic review summarizing the evidence regarding the specific sources of energy used in focal ablative therapy for prostate cancer. Overall, 37 articles reporting on 3,230 individuals undergoing focal therapy were selected. Thirteen reported on HIFU, 11 on cryotherapy, three on photodynamic therapy, four on laser interstitial thermotherapy, two on brachytherapy, three on IRE, and one on radiofrequency. Laser interstitial thermotherapy has been evaluated in up to stage 2a studies. The median follow-up varied between 4 months and 61 months, and the median rate of serious adverse events ranged between 0% and 10.6%. Pad-free, leak-free continence and potency were obtained in 83.3% to 100% and 81.5% to 100%, respectively. In series with intention to treat, the median rate of significant and insignificant disease at control biopsy varied between 0% and 13.4% and 5.1% and 45.9%, respectively. The authors concluded that while focal therapy seems to have a minor impact on QOL and genitourinary function, the oncological effectiveness has not been defined against the current standard of care. The authors identified limitations of this systematic review, including the length of follow-up, absence of a comparator arm, and study heterogeneity.

Transperineal Laser Ablation

Currently, there is insufficient evidence regarding the long-term effectiveness and safety of the use of TPLA. Identified literature includes two RCTs that both show inferiority of TPLA compared with TURP for effectiveness but show superiority on sexual adverse events. Additional evidence is limited by the lack of a comparison group.

A 2025 ECRI Clinical Evidence Assessment focused on the safety and efficacy of TPLA and compared it with those of TURP and other minimally invasive BPH treatments. Evidence from one systematic review showed that TPLA is safe, alleviates LUTSs, improves QOL through the 5-year follow-up, and does not negatively affect sexual function through the 3-year follow-up. However, most studies reported on short-term follow-up, assessed too few individuals per comparison, or were at a high risk of bias and varied in individuals' characteristics. It was concluded that the available evidence is insufficient to determine how well the safety and efficacy of TPLA compares with those of TURP and other minimally invasive treatments for improving outcomes.

Pacini et al. (2025) reported the short term results of a randomized trial comparing TPLA and water vapor ablation (Rezum System, Boston Scientific) for the treatment of BPH. Eighty participants were randomized 1:1 to receive one of the two interventions, with follow up at three and six months. Inclusion criteria were men 50 years of age or older, an IPSS > 7, uroflowmetry with a Qmax < 15 ml/s and a PVR ≥ 50 ml or indwelling bladder catheter, despite medical treatments, a PSA < 4 ng/ml and a negative digital rectal exam, a negative urine culture and prostate volume ≥ 30mL. The primary efficacy endpoint was the change in IPSS at three months. Outcomes were assessed at three and six months. The results showed overall significant improvement in IPSS favoring the TPLA group with 2.5 and 3 point differences at three and six months respectively. The QoL scores were similar across the two groups, with the TPLA group showing significantly higher scores at three months that did not persist to the final follow up. Significant improvements were seen with Qmax, Qmed and PVR in both groups at last follow up. Post operative complications were seen in a total of participants in both groups with four in the WVA group and two in the TPLA group experiencing hematuria that did not require continuous bladder irrigation, One participant required continuous bladder irrigation until the next day. One participant in the TPLA group, with a prostate volume > 200 ml developed a prostate abscess that required a transperineal drain and subsequent TURP. The number of acute urinary retentions after catheter retrieval were 3 in the TPLA group and 1 in the WVA group. Seven individuals in the TPLA group, and five in the WVA group were unavailable for six month follow up. In both groups, five participants underwent TURP more than three months after treatment, the remainder were lost to follow up. All participants that completed six month follow up were able to discontinue prostate medications. The authors concluded that both TPLA and WVA are safe and feasible to treat BPH, while acknowledging that the small sample size and short follow up limit the ability to draw firm conclusions. Specifically, the study was not designed as a non-inferiority trial with long-term follow up. Large studies with longer follow up are needed to validate these findings.

Zucchi et.al (2025) conducted an RCT in 80 participants that were randomized 1:1 to assess the impact on the preservation of erectile and ejaculatory function in participants receiving TPLA and convective water vapor ablation (CWVA) using the IIEF-5 and MSHQ-EjD questionnaires). Inclusion criteria was prostate volume > 30 ml, age > 50 years, IPSS > 7, PSA < 4 ng/ml, and maximum flow rate < 15 ml/s with post-void residual > 50 ml. In the preliminary assessment, 30 in the TPLA group and 31 in the CWVA group were sexually active. Baseline characteristics were comparable with the exception of prostate volume which was an average of 62 in the TPLA group, and 36 in the CWVA group, which was accounted for in the final analysis. The results showed that there were no significant differences in IIEF5 scores between the two groups at six-month follow up, however there was a transient decline in the TLPA group at three

months. The MSHQ-EjD scores showed significant improvement in both groups at six months. All patients treated included in the study were discharged the same day with clear urine, except for one in the TPLA group that required an overnight stay with continuous bladder irrigation. One participant in the TPLA group had a prostatic abscess. The authors concluded that both procedures are safe and feasible, and result in the preservation of erectile function and the recovery of ejaculatory function. This study is limited by a small sample size, short follow up and lack of a control group that includes conventional treatments for BPH.

Bertolo et al. (2023) conducted a single-center, prospective, randomized, open-label study to evaluate TPLA for the preservation of antegrade ejaculation compared with TURP with BPO. Participants must have had normal ejaculatory function and the presence of antegrade ejaculation prior to surgery, an IPSS score of ≥ 10, a Qmax of < 15 mL/s, a prostate volume at preoperative ultrasonography of < 100 mL, and normal preoperative urine analysis. The exclusion criteria included the presence of at least one of the following: previous prostate surgery; history of prostate cancer; history of urethral stricture; history of Marion disease; concomitant bladder stones; presence of median obstructive lobe (defined as > 1 cm of prostate abutting in the bladder lumen at preoperative ultrasonography); and neurological conditions that could potentially impact voiding. Overall, 51 participants were randomized 1:1 to receive TPLA (26) or TURP (25) and were assessed at 1 month post procedure. The results showed that there were no statistically significant differences in median catheterization time, but participants in the TPLA group had a higher rate of acute urinary retention after catheter removal. No participants required readmission. No significant differences were found regarding the IIEF-5 score, and the ejaculatory function status was unchanged in the treatment group; however, the control group had an 11-point decrease. The absence of antegrade ejaculation was reported by only one participant in the TPLA group compared with 18 in the TURP group. Uroflowmetry results showed that participants who received TURP had a mean improvement of 23.9 mL/s compared with 6.0 mL/s in the TPLA group. Both treatments showed statistically significant improvements in the IPSS and QOL scores, with TURP having a higher impact on IPSS. A significantly higher number of participants were satisfied with the treatment received in the TURP group vs. the TPLA group. The authors concluded that TPLA is superior to TURP in maintaining antegrade ejaculation. This study is limited by a small number of participants and short follow-up time. Furthermore, while TPLA appears to result in less sexual function harm than TURP, this study shows inferiority for the efficacy outcomes.

Tafuri et al. (2023) conducted a systematic review and meta-analysis to investigate the safety and efficacy of TPLA for the management of BPH-related LUTSs. Six articles (two retrospective and four prospective), comprising 287 individuals, were included. The primary outcomes were improvements in Qmax, PVR, and LUTS relief; secondary outcomes were preservation of sexual and ejaculatory function, as assessed by the IIEF-5 and MSHQ-EjD questionnaires, and rates of postoperative complications. Outcomes were assessed at 1, 3, 6, and 12 months post operation in all the studies. The results showed statistically significant improvement in mean Qmax, PVR, the IPSS, and QOL scores. For the four studies that reported on erectile function, there was no change in IIEF-5 scores at all follow-up time points; however, ejaculatory function showed improved MSHQ-EjD scores at each follow-up. Complication rates that were reported among the included individuals included one intraoperative urethral burn, two prostatic abscesses, four cases of hematuria, one case of orchitis, three cases of acute urinary retention, and six cases of transient dysuria. The authors concluded that TPLA shows promising results in pilot studies, and more research is needed to compare TPLA with standard treatments. This systematic review is limited by the lack of comparison groups, small number of individuals, and general low quality of the studies. (De Reinzo et al., 2021, and Pacella et al., 2020, previously cited in this policy, are included in this systematic review.)

In a 2023 prospective randomized controlled study, Canat et al. compared the first-year results with TURP vs. TPLA for the treatment of BPH. Overall, 50 participants aged 50 years or over who were candidates for TURP, with an IPSS of > 12 and Qmax of ≤ 15, were included and randomized 1:1 to receive TURP or TPLA. The IPSS, IIEF-5, MSHQ-EjD, and QOL assessments were completed by participants at baseline and at 12 months. Qmax, prostate volume, and PVR data were recorded. The results showed a statistically significant improvement in the IPSS, Qmax, and PVR compared with baseline values in both groups at 1 year, with the first-year Qmax values statistically significantly higher in the TURP group than in the TPLA group. IIEF-5 scores were similar in both groups, and MSHQ scores did not change in the TPLA group but were significantly decreased in the TURP group. PVR was similar in both groups. The authors concluded that BPH symptom improvement using TPLA is comparable to that with TURP, results in less ejaculatory dysfunction, and can be a treatment alternative in individuals who wish to preserve erectile function as well as those who are at a high anesthesia risk or cannot be taken off anticoagulation for surgery. This study is limited by a small number of participants and short-term follow-up, and larger studies, with longer follow-up, are needed to validate these findings.

Temporary Urethral Stents

The quality of the evidence is insufficient to support the efficacy and safety of this technology. One identified RCT provided mixed findings and had a large loss to follow-up, while one comparative observational study was limited by

indirect comparisons and did not demonstrate noninferiority compared with PUL regarding efficacy and serious treatment-related adverse event outcomes. Additional publications are limited by single-arm designs.

Amparore et al. (2021) reported the 3-year results of a prospective, single-arm, multicenter, international clinical study using the second generation of the temporary implantable nitinol device (iTind; Medi-Tate Ltd®, Israel) in 81 participants with LUTSs due to BPO. Baseline measurements included an IPSS of ≥ 10, peak urinary flow of < 12 ml/s, and prostate volume of < 75 ml. The outcomes assessed included operating room time, pain (visual analog scale), postoperative complications (Clavien-Dindo grading system), functional results (Qmax, the IPSS, and PVR), and QOL and were evaluated at 1, 3, and 6 months and 1, 2, and 3 years. Sexual and ejaculatory function were also evaluated. The results showed that all perioperative complications were Clavien-Dindo grade I or II, occurred in the short term, and were self-resolving. These included hematuria, urgency related to urination, pain, dysuria, and UTI. There were eight cases of urinary retention reported. At the 3-year follow-up, data were available for 50 of the original 81 participants, and the results showed that the efficacy of iTind remained stable, with significant improvements from baseline in the IPSS, QOL, Qmax, and PVR of -58.2%, -55.6%, +114.7%, and -85.4%, respectively (the intention-to-treat participant population included those participants who were identified as having median lobes, which was found to be a predictor for treatment failure between 12 and 24 months of follow-up). No adverse events were recorded between 12 and 36 months, and none of the participants who were previously sexually active reported sexual or ejaculatory dysfunction. From baseline to 24 months, five participants required drug therapy, and eight underwent surgical retreatment. The authors concluded that treatment of BPO with the iTind temporary implantable nitinol device showed significant and durable improvements at the 3-year follow-up. In 2023, Amparore et al. reported the long-term (50-79 months) results of this study. Due to the COVID-19 pandemic, participants could not be seen in person for objective tests for follow-up, adjustments to the planned follow-up protocol were required, and only IPSS and QOL scores could be assessed. The results showed prompt and sustained improvements in IPSS scores and QOL for up to 48 months. There were low rates of complications and adverse events, including UTI, hematuria, and postoperative pain, all of which occurred within 30 days and were self-resolving. There was no effect on erectile or ejaculatory function. This study is limited by the lack of a control arm comparing iTind with other procedures or sham and a small number of participants. Furthermore, due to the COVID-19 pandemic, only 50% of participants were available for more than 48 months of follow-up, and only subjective information was reported.

Chughai et al. (2020; included in ECRI Clinical Evidence Assessment) conducted an RCT that compared a temporarily implanted nitinol device (iTind) with sham in 175 participants with LUTSs due to BPH. The inclusion criteria for the participants were age 50 years or older; an IPSS of ≥ 10; a peak urinary flow rate of ≤ 12 mL/sec, with a 125-mL voided volume; and a prostate volume between 25 and 75 cc. Participants were randomized into either insertion of the iTind or a sham control group; the sham group received the insertion of a Foley catheter to simulate both implantation and retrieval of a temporary implanted device. The a priori primary outcome was changes in IPSS score at 3 months post procedure. In the intention-to-treat population, the iTind arm improved IPSS by -9.0 ±8.5 (22.1-13.0), while IPSS in the sham arm improved by -6.6 ±9.5 (22.8-15.8) ($p = 0.063$) at 3 months. A total of 78.6% of participants in the iTind arm had a reduction of ≥ 3 points in IPSS vs. 60% in the control arm at 3 months ($p = 0.029$). Adverse events occurred in 38.1% of participants in the iTind arm and 17.5% in the control arm. The study failed to identify significant differences between groups in peak urinary flow rate, QOL, and sexual function. The authors found iTind to be durable for 12 months, with only 4.7% of participants having undergone another surgical intervention for BPH. Overall, 78.6% of the participants receiving the iTind had improvement in their IPSS score. Limitations include the mixed results, loss to follow-up of almost 30% of participants, and specific inclusion criteria that could or could not be applied to all male individuals with BPH.

Ablation of Malignant Prostate Tissue by Magnetic Field Induction

There is insufficient evidence regarding the safety and efficacy of the ablation of malignant prostate tissue by magnetic field induction. The identified literature appears to be limited to a small, phase 1 trial.

Johannsen et al. (2007) conducted a prospective, phase 1 clinical trial in 10 participants with locally recurrent prostate cancer following treatment with a curative intent. The inclusion criteria also included a serum PSA value of < 20 ng/ml and an Eastern Cooperative Oncology Group performance status of 0 to 1. Participants were excluded if they had advanced imaging evidence of systemic disease, presence of secondary malignancies (other than well-controlled squamous cell carcinoma of the skin), metal implants located less than 30-cm distance from the prostate, chronic inflammatory diseases of the rectum and symptomatic bladder outlet obstruction, or significant voiding disorders. Three participants had local recurrence following radical or suprapubic prostatectomy, and the remaining seven had radio recurrent disease. All participants were either not suitable for or refused salvage radical prostatectomy. The primary end points included feasibility, toxicity, and QOL. Following intraprostatic injection of nanoparticles, six thermal therapy sessions of a 60-minute duration were delivered at weekly intervals using an alternating magnetic field. The results showed that while feasible in all participants, the same distribution of the magnetic fluid in preirradiated prostate tissue was difficult to achieve, and one received five thermotherapy sessions not six. Alternating magnetic field strengths of 4 to 5 kA/m were

tolerated throughout the treatment time in all participants. A minor rise in pulse and blood pressure occurred in some participants toward the end of treatments, and higher magnetic field strengths caused discomfort in the groin and/or perineal region. No systemic toxicity was observed. A transurethral or suprapubic catheter for 2 to 4 weeks due to acute urinary retention was necessary in four participants (all with previous history of urethral stricture/impaired urinary flow rate following radiation therapy). One participant experienced worsening urinary urge and frequency due to a bladder neck contraction; grade 3 urinary toxicity was noted in two participants, with both bladder spasms and urinary frequency (grade 3) in one and bladder spasms (grade 3) and urinary frequency (grade 2) in the other. In both cases, grade 3 side effects were observed only following magnetic nanoparticle injection and subsequent first thermal treatment. Grade 2 dysuria was present in two participants, and grade 1 was present in three participants. In one participant, a febrile UTI required antibiotic treatment. For QOL, there was no significant deterioration of physical functioning, global health status, and treatment-related symptoms during the study. However, there was significant deterioration of social functioning, role functioning, fatigue, pain, urinary symptoms, and sexual function. The authors concluded that the application of sufficiently high magnetic field strengths to achieve thermoablative temperatures may cause heating outside the target volume in a proportion of individuals as well as local discomfort during thermal treatments, and intratumor distribution of the nanoparticles is inconsistent and challenging. The authors stated that further research is needed.

Transurethral Drug-Coated Balloon

There is insufficient evidence regarding the safety and efficacy of this device. Existing evidence is limited by the lack of a comparison group beyond 3 months and lack of a comparison to established therapies.

In a 2024 ECRI Clinical Evidence Assessment, it was concluded that evidence from a multicenter, double-masked, sham-controlled RCT indicates that the Optilume® BPH system reduces BPH symptoms compared with sham and does not negatively affect sexual function. Symptoms in the control group remained at baseline or worsened. Evidence from two studies suggests that the efficacy of Optilume is maintained through the 4-year follow-up. No studies comparing Optilume with other BPH treatments were found.

In the 2023 PINNACLE study, a double-blinded, randomized, sham-controlled study, Kaplan et al. evaluated the safety and efficacy of a novel drug/device combination, the Optilume BPH Catheter System (Urotronic Inc., Plymouth, Minnesota) for the treatment of LUTSs due to BPH. Overall, 148 participants between 50 and 80 years old, with symptomatic BPH, an IPSS of ≥ 13, a Qmax between 5 and 12 mL/s, a prostate volume between 20 and 80 g, and a prostatic urethral length of 32 to 55, were randomized 2:1 to receive treatment with Optilume BPH or a sham procedure in which the balloon was not inflated. In total, 100 received the Optilume BPH, and 48 received a sham procedure. After the 3-month follow-up, participants in the sham arm were allowed to cross over to the treatment arm. The exclusion criteria included prior prostate procedures; a PSA of > 10, without a negative biopsy; diagnosis or suspicion of bladder or prostate cancer; an active UTI; PVR of > 300 mL; and any other condition that could impact urinary function. Blinding was maintained in participants and assessors through 1 year post procedure. Follow-up was conducted at 14 and 30 days and 6 and 12 months in both arms and included self-assessments and subjective measurements of uroflowmetry and PVR. The results showed a reduction in IPSS of an average of 11.5 at 1 year compared with an average of 8.0 in the sham arm at 3 months. The change in Qmax scores was also significantly improved in the treatment arm. PVR also improved from 83 mL at baseline to 58 mL at 1 year. Sexual function was not significantly impacted, and both arms had mild improvement. Four participants in the treatment arm reported an adverse ejaculatory dysfunction compared with one in the sham arm. No erectile dysfunction was reported. Four cases of postprocedural hematuria that required cystoscopy management or extended observation were reported as well as one urethral false passage that required extended catheterization. The authors concluded that the Optilume System produces clinically meaningful results for the treatment of LUTSs secondary to BPH immediately, and these are sustained through 1 year of follow-up. Further research, with longer follow-up times and comparison to established treatments for BPH, is needed to validate these findings. In 2024, Kaplan et al. reported the 2-year outcomes of this study. Overall, 77 of the participants in the treatment arm were available, and the results showed that at 2 years, 67% of the participants were responsive, as defined by a ≥ 30% improvement without any medical or surgical retreatment. IPSS scores improved by 50.8%, Qmax improved by 116% from 8.9 to 19.0, and PVR showed a slight reduction. BPHII improved from 7.0 to 2.3 at 1 year, and this remained consistent to 2 years. The most common adverse events were hematuria and UTI, and no device and/or serious adverse events were reported after 1 year. There was no impact on sexual function. Improvement in uroflowmetry measures was consistent across all prostate volumes. Surgical reintervention occurred in three participants in the treatment arm and included PAE, TURP, and laser ablation. The use of pharmacotherapy post treatment was seen in six participants and included α-blockers, phosphodiesterase 5 inhibitors, 5-α reductase inhibitors, and supplements. The authors concluded that at the 2-year follow-up in the PINNACLE study, participants treated with the Optilume BPH Catheter had sustained improvement in symptoms and functional outcomes, confirming effectiveness and longer-term outcomes, with a safety profile that is comparable to those of other minimally invasive treatments.

In 2021, Kaplan et al. reported the 1-year results from the EVEREST study, a prospective, single-arm, open-label, first-in-human study that evaluated the outcomes after treatment with the Optilume BPH Catheter System in 80 participants with moderate to severe LUTSs secondary to BPH. The EVEREST study was conducted in six centers in the Dominican Republic and Panama and included participants who were over the age 50 years and had an IPSS score of ≥ 13; peak Qmax of 5 to 15 mL/sec, with a minimum voided volume of ≥ 125 mL; PVR of ≤ 250 mL; prostate volume of 20 to 80 g; and prostatic urethra length of 35 to 55 mm. Participants were followed up at 2 to 5 days (catheter removal), 2 weeks, 30 days, 3 and 6 months, and 1 year. The primary end point was based on a modified intention-to-treat population and was a ≥ 40% improvement in IPSS scores at 3 months. Secondary measures included the IPSS, Qmax, pain, sexual function, and adverse events. In total, 75 of the original 80 participants were available for 1 year of follow-up, and the results showed that 81.3% of participants reached the primary end point at 3 months. The secondary end points all showed sustained improvement through 1 year of follow-up, with more than 70% having at least a 50% improvement in the IPSS from 30 days onward; approximately half achieved 75% improvement by 1 year. Qmax scores also increased from baseline through 1 year, and IPSS QOL improved by 70.7%. There was no deterioration in sexual function, and ejaculatory function was preserved. Overall, 113 adverse events were reported through the 1-year follow-up, and the majority occurred within 3 months of treatment; the most frequent were postprocedural hematuria (15.0%), postoperative urinary retention (13.8%), urinary incontinence (13.8%), UTI (8.8%), ejaculation disorder (8.8%), and dysuria (7.5%). The authors concluded that these results show that treatment with the Optilume BPH Catheter System is safe and can achieve rapid and sustain reduction in symptomatic LUTS. In 2024, Kaplan et al. reported the 4-year outcomes of this study. These results included the primary end points of functional assessments and symptomatology. Of the original 80 participants, 59 were available for this 4-year follow-up. At the 4-year follow-up, improvement was sustained in both storage and voiding sub scores, with approximately two-thirds of the overall improvement seen in the voiding domain. Sexual function, as measured by the IIEF and MSHQ-EjD, was preserved at 4 years, with no statistically significant change for any measure. A total of 136 adverse events were reported in 56 participants through 4 years, with the majority occurring within 3 months of the procedure and no treatment-related adverse events occurring from months 24 through 48. This longer-term follow-up shows that symptom improvement that was originally obtained from treatment with the Optilume catheter was sustained through 4 years. The findings of this study are limited by the single-arm design.

Transurethral Thermal Ultrasound Ablation

Transurethral thermal ultrasound ablation (TULSA) of the prostate has emerged as a minimally invasive treatment for prostate cancer that delivers precise doses of therapeutic ultrasound under MRI guidance. There is insufficient evidence regarding the safety, efficacy, and long-term outcomes of this treatment. Furthermore, existing research is limited by a lack of comparator groups as well as small numbers of individuals.

Tricard et al. (2025) conducted a prospective clinical trial to evaluate the safety and efficacy of the TULSA-PRO® device in the treatment of organ-confined, low- to intermediate-risk prostate cancer. Overall, 25 men with organ-confined, low- to intermediate-risk prostate cancer and a PSA of ≤ 15 ng/mL, ISUP of 1 or 2, and MRI classification ≤ iT2c, confirmed on biopsy, with or without previous prostate cancer treatment, were included. Additional criteria included a prostate volume of < 100 g, an Eastern Cooperative Oncology Group status of ≤ 1, and no contraindications to magnetic resonance or general anesthesia. Follow-up occurred at 1, 3, 6, and 12 months and included prostate questionnaires, uroflowmetry, PSA, and magnetic resonance–guided imaging. TRUS-guided biopsies were performed at 12 months. The primary outcome was clinically significant cancer following biopsy at 12 months. This was defined as an ISUP of ≥ 2, 1 with > 3 mm cumulative cancer on biopsy, or ISUP of 1 with more than two positive biopsies. The secondary outcomes included safety [assessed by the Society of Interventional Radiology (SIR) adverse event classification], QOL (IPSS, Urinary Symptom Profile, IIEF-15, and European Organisation for Research and Treatment of Cancer scores), PSA levels, salvage treatment–free survival rates, and early oncological effectiveness (defined as the proportion of participants with no detectable cancer). Overall, 24 TULSA procedures were completed, and there were no adverse events. The results showed that the mean PSA levels at 3, 6, and 12 months were 0.73 ng/mL, 1.1 ng/mL, and 0.93 ng/mL, respectively. At 12 months, 23 participants underwent prostate biopsy, and 15 biopsies were positive. Ten of these were clinically significant cancer, with seven undergoing salvage treatment (prostatectomy, radiation, and androgen deprivation therapy). Within the entire cohort of 25 participants, after a mean follow-up of 37.4 months, the intention-to-treat clinically significant cancer recurrence–free survival rate was 40%, treatment-free survival rate was 72%, metastasis-free survival and cancer-specific survival rates were 100%, and the overall survival rate was 96%. MRI follow-up at 1, 3, and 6 months showed no sign of recurrence. Of the 10 with cancer on biopsy, only three had a suspicious lesion on 12-month imaging. Uroflowmetry measures improved in all participants, and the IPSS QOL score worsened in 10. At the 1-year follow-up, the Urinary Symptom Profile questionnaire showed that six participants had stress urinary incontinence, eight had overactive bladder disorder, and two had voiding disorders. Thirteen participants had an IIEF score of > 10, and there was a mean decrease of 13.7 post treatment. Six participants experienced an adverse event, two of which were unrelated to the procedure. The adverse events that were procedure related included prostatitis and epididymitis/orchitis. The authors concluded that the TULSA procedure is safe and effective for treating organ-confined, low- to intermediate-risk prostate cancer. However, the small number of participants, short follow-up, and lack of comparison to established treatments are

limiting factors. Furthermore, including both participants with and without previous prostate cancer treatment is a confounding factor.

In 2021, Klotz et al. reported the 12-month safety and efficacy outcomes of the prospective, single-arm, multicenter, pivotal trial [TULSA-PRO Ablation Clinical Trial (TACT)], which used MRI-guided transurethral ultrasound ablation in 115 participants who had favorable- to intermediate-risk prostate cancer across 13 centers and were treated with whole-gland ablation, sparing the urethra and a 3-mm margin at the apical sphincter. Inclusion criteria were participants aged 45 to 80 years; a Gleason grade (GG) of 1 to 2 cancer, with clinical stage T2b or less; a PSA of 15 ng/ml or less; a minimum 10-core biopsy; no previous treatment; and the ability to undergo MRI. Participants were excluded if they had any of the following: a prostate greater than 90 cc, with width greater than 6 cm or length greater than 5 cm; implants incompatible with MRI; active infection; suspected tumor within 3 mm of the prostate apical plane on MRI; intraprostatic cysts; and calcifications greater than 1 cm. The safety results showed that a total of 12 severe (grade 3) adverse events occurred in nine participants and included infection, stricture urinary retention, urethral calculus and pain, and urinoma. All were resolved by the 12-month follow-up. At 12 months, 27 of the participants had moderate erectile dysfunction, and three had moderate urinary incontinence. Two participants had recurrent UTIs at 12 months. Urethral stricture occurred in three, urinary retention occurred in 10, and moderate abdominal or rectal discomfort was experienced. Efficacy results showed that at the 12-month follow-up, a reduction in PSA of greater than 75% was achieved in 110 participants (two of 115 participants had missing 12-month PSA values, which were interpolated from the 6-month visit). A median decrease of 91% in prostate volume in 111 participants at 12 months was also demonstrated. There was no evidence of cancer in 72 participants, and 16 had low-volume GG1. Participant-reported measures of erectile function and overall sexual function and satisfaction showed that there was an initial decrease in these domains, followed by gradual recovery, and ultimately, one-third experienced moderately decreased sexual function at 12 months. Overall, 92 participants were potent at baseline, and 69 regained or maintained potency at 12 months. The urinary incontinence domain scores declined at 1 to 3 months and recovered to baseline by 6 months. At 12 months, less than 1% of participants were incontinent, with 4% reporting more leakage than baseline. The primary PSA end point was met, as defined by regulators to assess the efficacy of TULSA as a prostate tissue ablation device. The authors concluded that TULSA is an effective ablative treatment for prostate cancer and has a favorable side effect profile, with minimal impact on QOL. This study is limited by a small number of participants, with a short follow-up time, and a lack of a comparator group.

In a 2020 prospective, single-center, phase 1 study, Anttinen et al. enrolled 11 men with biopsy-proven localized prostate cancer recurrence after radiotherapy to evaluate the safety and feasibility of TULSA as a salvage treatment (sTULSA). Biopsies were taken from all prostatic lesions suspicious for malignancy on MRI and/or 18F-PSMA-1007 positron emission tomography–computed tomography. In the absence of a visible lesion, systematic biopsies were taken. Staging ranged from T1 to T3; 10 had previous EBRT, and one had high dose rate. The median prostate volume was 21 cm^3, and the median PSA was 7.6 ng/ml. All participants underwent cystoscopy before sTULSA to ensure sufficient urethra patency for the device and underwent either whole- (n = 8) or partial-gland (n = 3) ablation, depending on disease characteristics. Follow-up occurred at 3-month intervals. The results showed that sTULSA was feasible in all participants. There was one grade 3 and three grade 2 urinary adverse events that included urinary infection and retention in four participants. Ten participants were free of catheterization at 1 year, with one participant who had received prior salvage brachytherapy remaining on intermittent catheterization. No bowel-related adverse events of any grade were observed. The declines in average flow rate and Qmax at 12 months were 27% and 24%, respectively, and the decrease in voided volume from baseline to 12 months was 54%. The only participant who had received a prior salvage treatment had an increase in PVR volume post treatment. Participant-reported functional outcomes showed an overall improvement at the 12-month follow-up, and three participants required mirabegron for urinary urgency. No lesions were observed at 3 months on multiparametric MRI, and at 12 months, 10 participants had no prostate cancer in the targeted ablation zone and had low and stable PSA. Two of the 11 participants had an out-of-field recurrence. The authors concluded that sTULSA appears to be safe and feasible for salvage treatment of radio recurrent prostate cancer. This study is limited by a small number of participants, lack of a comparison group, and short follow-up period.

Chin et al. (2016) conducted a prospective phase 1 trial to determine the safety and feasibility of MRI-TULSA for whole-gland prostate ablation for the treatment of prostate cancer. This trial was conducted at three urology centers in Canada, Germany, and the United States. Overall, 30 treatment-naive individuals aged ≥ 65 years, who had confirmed stage T1c to T2a, N0, M0 PCa, a PSA of ≤ 10 ng/ml, and a Gleason score of 3 + 3 or 3 + 4, were included. The primary end points were safety and feasibility up to 12 months. Follow-up visits were at 2 weeks and 1, 3, 6, and 12 months. Other end points that were explored were PSA, the IPSS, the erectile function domain of the IIEF-15, and the bowel habits domain of the UCLA-PCI-SF (University of California, Los Angeles Prostate Cancer Index-Short Form). The results showed that there was no of ablative heating thermometry of the external urinary sphincter or rectal wall. Immediate posttreatment necrosis correlated with the thermal pattern measured by MRI thermometry. Safety results showed no intraoperative complications, rectal injury or fistula, or severe urinary incontinence. There were no grade 4 or higher adverse events and only one attributable grade 3 event (epididymitis). The majority were grade 1 and grade 2 events that occurred and resolved within

the first 3 months and included approximately 10 UTIs. Cystoscopy was performed at the 12-month visit, specifically to assess urethral strictures, and showed an incidental finding of a grade 1 asymptomatic urethral stricture in one participant, requiring no action, and a grade 2 stricture that was resolved with a urethral dilator. The exploratory outcomes showed that median IPSS scores increased at 1 month, with a return to baseline at 3 months and symptom improvement in 17 participants. Median IIEF-15 erectile function decreased initially and returned to baseline by 12 months. Median PSA decreased by 87% at 1 month and was stable at the 12-month follow-up. An MRI and TRUS prostate biopsy at 12 months showed diminished prostate volumes, averaging 51% fibrosis. Biopsies were positive for clinically significant disease in nine of 29 participants. Positive biopsies for any disease were obtained in 16 of 29 participants and showed a 61% reduction in total cancer length. Two participants underwent prostatectomy after 12 months, and the remainder remain on per-protocol surveillance. The authors concluded that this phase 1 study achieved its feasibility and safety objectives by demonstrating (1) the ability to thermally ablate target tissues to within 1.3 mm and (2) well-tolerated side effects, with minor or no impact on urinary, erectile, and bowel function at 12 months. Oncological outcomes were not the primary or secondary outcomes assessed, so conclusions cannot be made. Furthermore, the safety requirement of the trial required targeting of the inner 90% of the prostate, without an attempt to target specific foci; this had implications for oncological outcomes, as prostate cancers are typically found at the periphery of the gland. Additionally, MRI was not used for staging at baseline, which may have led to suboptimal staging and treatment, likely leading to the high rate of salvage treatment at the 3-year follow-up. The authors stated that these trial data provide evidence for further study of MRI-TULSA in larger populations of individuals. In 2021, Nair et al. reported on the 3-year outcomes of this clinical trial in 22 of the 30 participants. The outcome assessment included adverse events, functional QOL, and PSA as well as biopsy, feasibility, and safety. At the 3-year follow-up, 22 participants had remained in protocol-mandated follow-up. One withdrew after refusing the 12-month biopsy, and seven received subsequent treatment other than TULSA, which was not permitted by the study protocol. The results showed that a 12-core TRUS biopsy, taken in 29 participants (10 at only 12 months and 19 with biopsies at 12 and 36 months), showed significant, clinically positive results during follow-up. Ten participants had a clinically significant biopsy finding, and 17 had any positive biopsy findings. Of 13 participants with negative biopsies at 12 months, all are continuing per-protocol follow-up. Of the seven participants who were positive for insignificant disease at the 12-month biopsy, four underwent salvage radical prostatectomy. Of the nine participants who had clinically significant disease at 12 months, five had salvage treatment. Biochemical recurrence was seen in eight participants, with an estimated 3-year biochemical recurrence–free survival of 74%. Safety results showed no adverse events ≥ 4 and no rectal injuries or fistulae, and no new significant adverse events were developing between 12 and 36 months. Most of the adverse events at 12 months resolved before the 3-year visit, and there were 12 adverse events ongoing in 10 participants. There were no significant differences in erectile function, bowel function, urinary incontinence, or the IPSS between baseline and 3 years. The authors concluded that this 3-year follow-up confirms the safety and durability of TULSA for treating men with localized prostate cancer. This 3-year follow-up is limited by the same limitations of the original study regarding oncological outcomes as well as a lack of a comparison group.

Irreversible Electroporation Ablation

There is insufficient evidence regarding the safety, efficacy, and long-term outcomes of IRE for treating prostate cancer. Evidence is limited by the lack of a comparison group, lack of comparison to established treatments, and/or short-term follow-up.

In a 2025 Hayes Evolving Evidence Review on the NanoKnife System for the treatment of localized prostate cancer, it was concluded that the evidence to date is of poor quality; therefore, the safety and efficacy are unclear, and there is minimal support in the published literature. However, there are several clinical trials currently recruiting as well as multiple studies with ongoing follow-up.

A 2025 ECRI Evidence Analysis on IRE for treating prostate cancer concluded that based on evidence from four systematic reviews with overlapping data, one nonrandomized comparison study, and three single-arm studies, IRE works as it is intended to ablate prostate tumors in the short term, without serious adverse events. However, studies lack direct comparison to standard of care or other ablation techniques. Larger controlled and comparison studies, with long-term follow-up, are needed.

In a 2025 prospective, nonrandomized, single-arm, pivotal trial (the PRESERVE study), George et al. (2025) assessed the safety and effectiveness of IRE with the NanoKnife System to ablate prostate tissue in participants with intermediate-risk prostate cancer. The study enrolled 128 participants over 50 years of age who had MRI-visible, fusion biopsy–proven, organ-confined stage < T2c prostate cancer. Additional enrollment requirements included PSA of ≤ 15 ng/ml or, if PSA was > 15 ng/ml, a PSA density of < 0.15 ng/ml^2 and GG group of 2 or 3. Participants were treated with the NanoKnife System using a treatment margin of ≥ 10 mm and followed up at 3 to 10 days and at 1, 3, 6, 9, and 12 months. The primary outcome was the number of participants with a negative in-field biopsy for any GG cancer at 12 months. Adverse events and participant-reported outcomes were assessed at each follow-up visit. The results showed that at 12 months, 71% had a negative in-field biopsy. The Delphi consensus for the absence of clinically significant prostate cancer was

used, and treatment success was seen in 81%. The rate of negative out-of-field biopsies at 12 months was 64%, and among the 40 participants with positive out-of-field biopsies, 50% had GG1, 33% had GG2, 13% had GG3, 2.5% had GG4, and 2.5% were unknown. At 12 months, the rate of any prostate cancer occurrence was 45%, and clinically significant prostate cancer anywhere was seen in 26%. PSA levels showed a 3.4-ng/ml decrease after 12 months, and the prostate volume decreased by 16.3% and 16% at 3 and 12 months, respectively. Two participants had persistent disease at the 3-month MRI and underwent additional IRE and salvage prostatectomy. Regarding safety end points, 86% of participants experienced an adverse event, with the most common being hematuria. Overall, 14 participants experienced a grade 3 adverse event that included abdominal pain, urinary retention, and a rectourethral fistula. The authors concluded that IRE shows promising short-term oncological outcomes and is a viable treatment option in select individuals with localized prostate cancer. This study is limited by a very small number of participants, lack of a comparator arm, and manufacturer funding. Additional robust, independent research is needed to validate these findings.

Nerve Graft to Restore Erectile Function During Radical Prostatectomy

There is insufficient quality scientific evidence in the clinical literature demonstrating that using nerve grafting results in improved outcomes for erectile dysfunction following radical prostatectomy. Single-arm and nonrandomized observational studies suggest a possible benefit, but one available randomized trial ended early due to lack of benefit at the intermediate analysis. This suggests that the findings of the nonrandomized studies may have been biased. Some of these nonrandomized studies did show baseline differences in individuals undergoing nerve grafting compared with those not undergoing this procedure.

Harke et al. (2023) conducted a case series to investigate the safety and feasibility of spider silk grafting for erectile nerve reconstruction in participants undergoing robotic radical prostatectomy. The major ampullate dragline from Nephila edulis was used for spider silk nerve reconstruction (SSNR). After removal of the prostate with either unilateral nerve sparing (UNS) or bilateral nerve sparing (BNS), the spider silk was laid out on the site of the neurovascular bundles. Data analysis included inflammatory markers and participant-reported outcomes. Six participants underwent robotic radical prostatectomy with SSNR. In 50% of the cases, only UNS was performed; BNS could be performed in three people. The placement of the spider silk conduit was uneventful; contact of the spider silk with the surrounding tissue was mostly sufficient for a stable connection with the proximal and distal ends of the dissected bundles. Inflammatory markers peaked until postoperative day 1 but stabilized until discharge, without any need for antibiotic treatment throughout the hospital stay. One participant was readmitted due to a UTI. Three people reported erections that were sufficient for penetration after 3 months, with a continuous improvement of erectile function both after BNS and UNS with SSNR up to the last follow-up after 18 months. The authors concluded that in this analysis of the first robotic radical prostatectomy with SSNR, a simple intraoperative handling, without major complications, was demonstrated. While the series provides evidence that SSNR is safe and feasible, a prospective randomized trial, with long-term follow-up, is needed to identify further improvement in postoperative erectile function due to the spider silk–directed nerve regeneration. Given the nonrandomized design of this study and the retrospective nature of the data collection and analysis, one cannot rule out residual confounding factors that could influence the results. Further research is needed to determine the clinical relevance of these findings.

Shauly et al. (2019) conducted a systematic review of recent articles and identified 19 articles/studies addressing relatively new interventions for erectile dysfunction. The review documented evidence supporting the use of two microsurgical treatments for erectile dysfunction: microvascular arterial bypass penile revascularization surgery and cavernous nerve graft reconstruction. For cavernous nerve graft reconstruction, the authors identified six publications, but they were limited by the lack of a comparison group. Although the authors indicated that their analysis served to organize the most up-to-date data in treating erectile dysfunction and showed promise, they concluded that many of the studies lacked a large enough study population to make material claims, and further clinical evidence is required.

Reece et al. (2019) performed a retrospective review of a single-center experience of nerve grafting in a case series of 17 men who had erectile dysfunction following radical prostatectomy surgery. Microsurgical bilateral end-to-side nerve grafts from a selective fascicular neurotomy of the femoral nerve to the penile corpora cavernosa were performed. The median age at nerve grafting was 64 years. The median time between nerve- and non-nerve-sparing radical prostatectomy and nerve grafting was 2.4 and 2.2 years, respectively. The median follow-up was 18 months. At 12 months after nerve grafting, 71% (95% CI, 44%-90%) of people had erectile function recovery sufficient for satisfactory sexual intercourse, and 94% (95% CI, 71%-99%) and 82% (95% CI, 57%-96%) had clinically significant improvements in sexual function and reduced bother, respectively. There were two minor wound infections. The authors indicated that this provided confirmatory evidence that end-to-side nerve grafting surgery restored erectile function and improved sexual QOL in, respectively, 71% and 94% of men with erectile dysfunction following radical prostatectomy. The authors recognized that the limitations include the retrospective study design and concluded that larger studies to determine erectile function recovery rates using end-to-side nerve grafting to restore erectile function in men with post–radical prostatectomy erectile

dysfunction are advised to confirm the procedure's efficacy and feasibility. The findings are limited by the lack of a comparison group.

Souza Trindade and colleagues (2017) conducted a long-term case series study in 10 individuals at 6, 12, 18, and 36 months post operation who had surgery involving bridging of the femoral nerve to the dorsal nerve of the penis and the inner part of the corpus cavernosum with sural nerve grafts and end-to-side neurographies after undergoing a radical prostatectomy at least 2 years prior. Four individuals also underwent radiotherapy after radical prostatectomy. All individuals reported satisfactory sexual activity prior to radical prostatectomy. The surgery involved bridging of the femoral nerve to the dorsal nerve of the penis and the inner part of the corpus cavernosum with sural nerve grafts and end-to-side neurographies. Individuals were evaluated using the IIEF questionnaire and Pharmaco-Penile Doppler Ultrasonography prior to the operation and at 6, 12, and 18 months post operation and using a Clinical Evolution of Erectile Function questionnaire, which was administered after 36 months. The IIEF scores showed improvements regarding erectile dysfunction, satisfaction with intercourse, and general satisfaction. Evaluation of Pharmaco-Penile Doppler Ultrasonography velocities did not reveal any difference between the right and left sides or among the different time points. The introduction of nerve grafts neither caused fibrosis of the corpus cavernosum nor reduced penile vascular flow. Clinical Evolution of Erectile Function results showed that sexual intercourse began after a mean of 13.7 months, with frequency of sexual intercourse varying from once daily to once monthly. The authors concluded that a total of 60% of individuals were able to achieve full penetration, on average, 13 months after reinnervation surgery. Those who previously submitted to radiotherapy had a slower return of erectile function. The authors concluded that penile reinnervation surgery is a viable technique, with effective results, and could offer a new therapeutic option for erectile dysfunction after radical prostatectomy. This study is limited by the small number of cases (n = 10) and lack of a comparison group.

Kung et al. (2015) performed a retrospective study in 38 consecutive patients who underwent immediate unilateral or bilateral nerve reconstruction after open prostatectomy. Additionally, 53 control patients who underwent unilateral, bilateral, or non-nerve-sparing open prostatectomy without nerve grafting were reviewed. Outcomes included rates of urinary continence, erections sufficient for sexual intercourse, and the ability to have spontaneous erections. Analysis was performed by stratifying patients by D'Amico score and laterality of nerve involvement. There was no significant benefit for patients who had unilateral nerve grafting vs UNS prostatectomy. Patients with BNS had superior functional outcomes compared with those with bilateral non–nerve sparing, whereas those with bilateral nerve grafting had a trend toward functional improvement. With increasing D'Amico score, there was a trend toward worsening urinary continence and erectile function, regardless of nerve-grafting status. The authors concluded that immediate nerve grafting for reconstruction of the prostatic plexus after radical prostatectomy may be most valuable for improving postoperative morbidity in those requiring bilateral neurovascular bundle resections. Currently, the benefit of nerve grafting is limited by the inability to accurately isolate the putative nerves, which mediate erectile function and urinary continence. Further investigation is needed to improve the potential of bilateral nerve grafting after non-nerve-sparing prostatectomy. Limitations to this study include the small sample size, subjective nature of the postoperative outcomes, and lack of randomization to intervention groups.

Siddiqui et al. (2014) examined the long-term outcome of sural nerve grafting (SNG) during radical retropubic prostatectomy (RRP) performed by a single surgeon. Overall, 66 individuals who had clinically localized prostate cancer, had a preoperative IIEF score of > 20, and underwent RRP were included. Neurovascular bundle excision was performed if the risk of side-specific extracapsular extension was > 25% on the Ohori nomogram. SNG was harvested by a plastic surgeon contemporaneously as the urological surgeon was performing RRP. The IIEF questionnaire was used prior to the operation, post operation, and at follow-up (3 years). Recovery of potency was defined as a postoperative IIEF-EF domain score of > 22. There were 43 (65%) unilateral SNGs and 23 (35%) bilateral SNGs. The mean preoperative IIEF score was 23.4 +1.6. The long-term assessment reflected that 19 individuals (28.8%) had IIEF scores of > 22. The IIEF-EF scores in those who had unilateral SNG and bilateral SNG were 12.9 +4.9 and 14.8 +5.3, respectively. The authors concluded that (1) SNG can potentially improve erectile function recovery in potent men who have higher-stage prostate cancer and are undergoing radical prostatectomy and (2) the contemporaneous, multidisciplinary approach provides a good-quality graft while expediting the procedure, without interrupting the workflow. However, the evidence is insufficient to conclude that this surgical technique is equivalent to BNS prostatectomy or that long-term outcomes are improved by nerve grafting. The findings are limited by the lack of a relevant comparison group.

Davis et al. (2009) evaluated whether UNS radical prostatectomy plus SNG would result in a 50% relative improvement in potency at 2 years compared with UNS radical prostatectomy alone. The plan was to enroll 200 participants from October 2001 to May 2006 in an RCT from a single academic center. After 107 participants were randomized in a 3:2 ratio (66 SNG; 41 controls), a protocol-planned interim analysis was performed, which reflected potency rates of 18 of 41 (44%) in the SNG group and 10 of 23 (43%) in the control group. Based on slower-than-estimated accrual (eight per month planned vs. two per month actual) and a < 5% posterior probability that the groups would show a difference, the data

monitoring committee recommended early termination of the trial. Using data gathered from the 107 participants, the authors concluded that in this single-institution randomized study, unilateral SNG did not result in an increased potency rate at 2 years compared with UNS radical prostatectomy alone, based on a threshold significance level of at least a 20% (absolute) improvement. Secondary end points also did not show an improvement in time to potency or urinary function at 1 year. Based on the power of this study, a smaller benefit could not be excluded. The authors believed that future study designs should anticipate inconsistent adherence with penile rehabilitation and 20% to 30% participant attrition.

Sugimoto et al. (2009) evaluated 24 individuals who underwent UNS with contralateral cavernous nerve grafting or bilateral nerve grafting and 64 individuals who underwent prostatectomy without a nerve-sparing procedure. Individuals in the nerve-grafting group who recovered potency had higher sexual function scores than those without a nerve-sparing procedure. However, the majority of these individuals were not satisfied with their sexual function. The findings are limited by the lack of randomization and small sample size.

Kuwata et al. (2007) prospectively investigated health-related QOL, including sexual function, in 66 participants who underwent nerve grafting during a radical prostatectomy compared with those who underwent a non-nerve-sparing radical prostatectomy (22 participants had nerve-grafting procedures; 44 underwent non-nerve-sparing and non-nerve-grafting procedures). The observation periods ranged from 12 to 46 months (median, 29 months). In participants who had nerve-sparing graft procedures (bilateral or unilateral), the sexual function score was significantly better than in the non–nerve-sparing/non–nerve-grafting participants. However, the sexual bother score was more serious for the participants who underwent nerve-grafting surgery than for the non–nerve-sparing/non–nerve-grafting participants. The findings are limited by the lack of randomization and small sample size.

Saito et al. (2007) evaluated 64 individuals who underwent a radical prostatectomy and intraoperative electrophysiological confirmation of cavernous nerve preservation. Overall, 12 individuals underwent a unilateral SNG for the resected neurovascular bundle. In total, 21 and 31 individuals underwent BNS and UNS surgery without a nerve graft, respectively. As the individuals were significantly younger in the SNG group than in the other groups, an age-matched analysis was also conducted. In the age-matched analysis, the postoperative sexual function score in the SNG group showed an intermediate level of recovery between those of the BNS and UNS groups at 12 months and reached the same level as the score at 12 months of the BNS group at 18 months post operation. The difference in the sexual function score between the SNG and UNS groups began to appear after 6 months post operation and increased steadily with time. However, the background factors, such as the baseline sexual function score, usage rate of phosphodiesterase 5 inhibitors, and rate of comorbidities, were different between the SNG and UNS groups.

A prospective observational study by Namiki et al. (2007) evaluated 113 participants undergoing RRP for the rate of recovery of urinary continence and sexual potency. Participants were classified into three groups according to the degree of nerve sparing: unilateral nerve preservation with contralateral SNG interposition, BNS, and UNS. The BNS group had the fastest recovery, although by 24 months, there were no significant differences observed between the BNS group and the UNS group with SNG. The BNS group reported a better sexual function score than the UNS group throughout the postoperative period. During the first year post operation, the BNS group and the UNS group with SNG had better urinary function results than the UNS group. The authors concluded that the nerve graft procedure may contribute to the recovery of urinary function as well as sexual function after RRP. These findings are limited by the lack of randomization.

Clinical Practice Guidelines

American Urological Association (AUA)

In 2023, the AUA revised their 2021 clinical guidelines on the surgical management of BPH/LUTSs. Included in their guideline statements are the following:

- PUL should be considered as a treatment for patients with LUTSs attributed to BPH, provided that the prostate volume is 30 to 80 g and there is a verified absence of an obstructive middle lobe (moderate recommendation; evidence level: grade C).
- PUL may be offered to eligible patients who desire preservation of erectile and ejaculatory function (conditional recommendation; evidence level: grade C).
- Robotic water jet treatment may be offered to patients, provided that the prostate volume is of > 30/< 80 g (conditional recommendation; evidence level: grade C).
- Water vapor thermal therapy:
    - Should be considered as a treatment option for patients with LUTSs/BPH with a prostate volume of 30 to 80g. Patients should be informed that evidence of efficacy, including longer-term retreatment rates, remains limited (conditional recommendation; evidence level: grade C).
    - May be offered as a treatment option for patients who desire preservation of erectile and ejaculatory function (conditional recommendation; evidence level: grade C).

- PAE may be offered for the treatment of LUTSs/BPH and performed by clinicians trained in this procedure (conditional recommendation; evidence level: grade C).
- Temporary implanted prostatic devices may be offered as a treatment option for patients with LUTSs/BPH, provided that the prostate volume is between 25 and 75 g and there is a lack of an obstructive median lobe (expert opinion).
- 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).

American Urological Association (AUA)/American Society for Radiation Oncology (ASTRO)

The 2022 AUA/ASTRO guidelines for clinically localized prostate cancer, which are endorsed by the Society of Urologic Oncology (SUO), state the following:

- For patients with favorable, intermediate-risk prostate cancer, clinicians should discuss active surveillance, radiation therapy, and radical prostatectomy (strong recommendation; evidence level: grade A).
- Clinicians should inform patients with intermediate-risk prostate cancer considering whole-gland or focal ablation that there are a lack of high-quality data comparing ablation outcomes with radiation therapy, surgery, and active surveillance. These procedures should not be recommended outside of a clinical trial (expert opinion).
- For patients with unfavorable, intermediate- or high-risk prostate cancer and an estimated life expectancy of greater than 10 years, clinicians should offer a choice between radical prostatectomy or radiation therapy plus androgen deprivation therapy (strong recommendation; evidence level: grade A).

American Urological Association (AUA)/American Society for Radiation Oncology (ASTRO)/ Society of Urologic Oncology (SUO)

In a 2024 joint guideline on salvage therapy for prostate cancer, the AUA, ASTRO, and SUO (endorsed by the American Society of Clinical Oncology) state that in patients with biopsy-documented prostate cancer recurrence after primary radiation therapy who are candidates for salvage local therapy, clinicians should offer radical prostatectomy, cryoablation, HIFU, or reirradiation as part of a shared decision-making approach (moderate recommendation; evidence level: grade C).

National Comprehensive Cancer Network (NCCN)

The clinical practice guidelines for the treatment of prostate cancer include the following:

- Cryotherapy: The guidelines state that “cryotherapy or other local therapies are not recommended as routine primary therapy for localized prostate cancer due to lack of long-term data comparing these treatments to radiation or radical prostatectomy.” Currently, the NCCN recommends cryosurgery and HIFU (Category 2B) as the only local therapy options for radiation therapy recurrence in the absence of metastatic disease.
- Radical prostatectomy: The guidelines state that radical prostatectomy is appropriate for any patient with cancer that is clinically localized to the prostate and can be completely surgically excised and who has a life expectancy of ≥ 10 years, without comorbidities that would contraindicate an elective surgery. Radical prostatectomy is listed as an option for patients with high-risk disease and in select patients with very high-risk disease. It may also be a treatment option for patients with biochemical recurrence after primary EBRT, but incontinence, erectile dysfunction, and bladder neck contracture remain significantly higher than when radical prostatectomy is used as initial therapy.

National Institute for Health and Care Excellence

The 2023 NICE interventional procedures recommendation for transurethral water jet ablation for LUTSs caused by BPH states that there is good-quality evidence that the procedure improves LUTSs caused by BPH and that it is safe to consider it as a treatment option.

A 2020 NICE medical technology guideline for the use of Rezūm for treating LUTSs secondary to BPH states that the evidence supports adopting Rezūm for treating LUTSs caused by BPH. It should be considered as a treatment option for men with moderate to severe LUTSs (IPSS typically 13 or over) and a moderately enlarged prostate (typically between 30 and 80 cm).

The 2018 NICE guidelines for PAE for LUTSs caused by BPH state that the current evidence of the safety and efficacy is adequate to support the use of this procedure, provided that standard arrangements are in place for clinical governance, consent, and audit. Furthermore, patient selection should be done by a urologist and an interventional radiologist. This procedure is technically demanding and should only be done by an interventional radiologist with specific training and expertise in PAE.

A 2012 NICE guideline on focal therapy using cryoablation for localized prostate cancer states that while there are no major safety concerns, the evidence on efficacy is limited, and there is concern that prostate cancer is often multifocal. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit, or research, making sure that patients and their carers understand the uncertainty.

Society of Interventional Radiology (SIR)

In a 2019 (McWilliams et al.) multisociety, evidence-based position statement regarding PAE for the treatment of LUTSs due to BPH, the SIR states that PAE is a safe and effective treatment, has good short- and intermediate-term efficacy, and is a treatment option for the following:

- For appropriately selected men with BPH and moderate to severe LUTSs (strong recommendation).
- In patients with BPH and moderate to severe LUTSs who have very large prostate glands (> 80 cm^3), without an upper limit of prostate size (moderate recommendation).
- In patients with BPH and acute or chronic urinary retention in the setting of preserved bladder function as a method of achieving catheter independence (moderate recommendation).
- In patients with BPH and moderate to severe LUTSs who wish to preserve erectile and/or ejaculatory function (weak recommendation).
- In patients with hematuria of prostatic origin as a method of achieving cessation of bleeding (strong recommendation).
- In patients with BPH and moderate to severe LUTSs who are deemed not to be surgical candidates for any of the following reasons: advanced age, multiple comorbidities, coagulopathy, or inability to stop anticoagulation or antiplatelet therapy (moderate recommendation).
- PAE should be included in the individualized patient-centered discussions regarding treatment options (strong recommendation).

The SIR also gives a strong recommendation that interventional radiologists, given their knowledge of arterial anatomy, advanced microcatheter techniques, and expertise in embolization procedures, are the specialists best suited for the performance of PAE.

European Association of Urology (EAU)

The 2023 EAU guidelines for the treatment of non-neurogenic male LUTSs, including BPO, state that the following interventions may be offered, with a strong strength of recommendation:

- Bipolar or monopolar TURP to surgically treat moderate to severe LUTSs in men with a prostate size of 30 to 80 mL.
- Transurethral incision of the prostate to surgically treat moderate to severe LUTSs in men with a prostate size of < 30 mL, without a middle lobe.
- Open prostatectomy in the absence of bipolar transurethral enucleation of the prostate and holmium laser enucleation of the prostate to treat moderate to severe LUTSs in men with a prostate size of > 80 mL.
- PUL (UroLift) to men with LUTSs who are interested in preserving ejaculatory function, with prostates of < 70 mL and no middle lobe.
- Laser enucleation of the prostate using the Ho:YAG laser (HoLEP) in men with moderate to severe LUTSs as an alternative to TURP or open prostatectomy.

The following interventions are given with a weak strength of recommendation:

- Laser resection of the prostate using Tm:YAG laser (ThuVARP) as an alternative to TURP.
- Bipolar transurethral (plasmakinetic) enucleation of the prostate in men with moderate to severe LUTSs as an alternative to TURP.
- Enucleation of the prostate using the Tm:YAG laser (ThuLEP, ThuVEP) in men with:
  - Moderate to severe LUTSs as an alternative to TURP, holmium laser enucleation, or bipolar transurethral (plasmakinetic) enucleation.
  - In patients receiving anticoagulant or antiplatelet therapy.
- 120-W 980-nm, 1,318-nm, or 1,470-nm diode laser enucleation of the prostate in men with moderate to severe LUTSs as a comparable alternative to bipolar transurethral (plasmakinetic) enucleation or bipolar TURP.
- PAE for men with moderate to severe LUTSs, who wish to consider minimally invasive treatment options and accept less optimal outcomes compared with TURP, to only be performed in units with highly trained teams.
- Aquablation in patients with moderate to severe LUTSs and a prostate volume of 30 to 80 mL as an alternative to TURP.

The EAU states that minimally invasive simple prostatectomy is feasible in men with prostate sizes of > 80 mL who need surgical treatment and that further RCTs are needed.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

On December 20, 2013, the FDA cleared the UroLift System (Teleflex Inc., Pleasanton, CA) for marketing through the 510(k) pathway. It is indicated for the treatment of symptoms due to outflow obstruction secondary to benign prostatic hyperplasia (BPH), including lateral and median lobe hyperplasia, in men aged 45 years or older. Refer to the following website for additional information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K193269. (Accessed October 31, 2025)

On August 2, 2019, the FDA cleared the Rezūm Water Vapor Therapy system (Boston Scientific Corp.) under the 510(k) premarket approval process for the treatment of symptoms of BPH and treatment of the prostate with hyperplasia of the central zone and/or a median lobe. It is not approved for the treatment of malignant prostate tissue. Refer to the following website for additional information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K191505. (Accessed October 31, 2025)

The FDA approved the Spanner® Temporary Prostatic Stent (SRS Medical, North Billerica, MA) under its premarket approval process on December 14, 2006. It is intended to be used for up to 30 days to maintain urine flow and allow voluntary urination in men following minimally invasive procedures for BPH after initial posttreatment catheterization. Refer to the following website for additional information: https://www.accessdata.fda.gov/cdrh_docs/pdf6/p060010a.pdf. (Accessed November 6, 2024)

In June 2021, the FDA cleared the iTind under its 510(k) premarket notification process. It is intended to treat urinary outflow obstruction secondary to BPH in men aged 50 years or over. Refer to the following website for additional information: https://www.accessdata.fda.gov/cdrh_docs/pdf21/K210138.pdf. (Accessed November 6, 2025)

On March 3, 2021, the AquaBeam® Robotic System (PROCEPT BioRobotics, Redwood City, CA) received 510(k) approval as a Class II device. It is intended for the resection and removal of prostate tissue in male individuals with lower urinary tract symptoms due to benign prostatic hyperplasia. Refer to the following website for further information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K202961. (Accessed October 31, 2025)

The ECHOLASER X4 system received 510(k) premarket notification from the FDA in September 2018. The device is intended for use in cutting, vaporization, ablation, and coagulation of soft tissue and in the treatment and/or removal of vascular lesions (tumors). For additional information, refer to the following website: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed November 6, 2024)

On January 2, 2020, the Optilume Urethral Drug Coated Balloon (Urotronic, Minneapolis, MN) received FDA clearance under the premarket approval pathway. It is indicated for the treatment of obstructive urinary symptoms associated with BPH in men ≥ 50 years of age. For additional information, refer to the following website: https://www.accessdata.fda.gov/cdrh_docs/pdf19/K191061.pdf. (Accessed October 31, 2025)

High-intensity ultrasound ablation systems have received FDA clearance under the 510(k) pathway. For additional information, refer to the following website, and search using product code PLP: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed October 31, 2025)

On October 24, 2011, the NanoKnife (AngioDynamics, Inc., Sunnyvale, CA) received 510(k) approval from the FDA for the surgical ablation of soft tissue using six outputs. On December 6, 2024, the FDA updated its approval indications for the NanoKnife to include the ablation of prostate tissue. For additional information, refer to the following website: https://www.accessdata.fda.gov/cdrh_docs/pdf24/K242687.pdf. (Accessed October 8, 2025)

Sural nerve transplant is a procedure and therefore not subject to FDA regulation.

References

Abt D, Hechelhammer L, Müllhaupt G, et al. Comparison of prostatic artery embolization (PAE) versus transurethral resection of the prostate (TURP) for benign prostatic hyperplasia: randomized, open label, non-inferiority trial. BMJ. 2018 Jun 19;361:k2338.

Abt D, Müllhaupt G, Hechelhammer L, et al. Prostatic artery embolization versus transurethral resection of the prostate for benign prostatic hyperplasia: 2-yr outcomes of a randomized, open-label, single-center trial. Eur Urol. 2021 Jul;80(1):34-42.

Albarqi HA, Demessie AA, Sabei FY, et al. Systemically delivered magnetic hyperthermia for prostate cancer treatment. Pharmaceutics. 2020 Oct 25;12(11):1020.

American Cancer Society. Cryotherapy, HIFU, and other ablative treatments for prostate cancer. November 2023.

American Society of Anesthesiologists (ASA). Standards and Practice Parameters. Statement on ASA Physical Status Classification System. Last amended December 13, 2020.

American Urological Association (AUA). Clinically localized prostate cancer: AUA/ASTRO Guideline 2022. Available at: https://www.auanet.org/guidelines-and-quality/guidelines/clinically-localized-prostate-cancer-aua/astro-guideline-2022. Accessed October 29, 2025.

American Urological Association (AUA). Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia: AUA Guideline. Available at: https://www.auanet.org/guidelines-and-quality/guidelines/benign-prostatic-hyperplasia-(bph)-guideline. Accessed October 29, 2025.

American Urological Association (AUA). Salvage therapy for prostate cancer: AUA/ASTRO/SUO guideline 2024. Available at: https://www.auanet.org/guidelines-and-quality/guidelines/salvage-therapy-for-prostate-cancer. Accessed October 29, 2025.

Amparore D, De Cillis S, Schulman C, et al. Temporary implantable nitinol device for benign prostatic hyperplasia-related lower urinary tract symptoms: over 48-month results. Minerva Urol Nephrol. 2023 Jun 23.

Amparore D, Fiori C, Valerio M, et al. 3-Year results following treatment with the second generation of the temporary implantable nitinol device in men with LUTS secondary to benign prostatic obstruction. Prostate Cancer Prostatic Dis. 2021 Jun;24(2):349-357.

Anttinen M, Mäkelä P, Viitala A, et al. Salvage magnetic resonance imaging-guided transurethral ultrasound ablation for localized radiorecurrent prostate cancer: 12-month functional and oncological Results. Eur Urol Open Sci. 2020 Nov 25;22:79-87.

Bach T, Gilling P, El Hajj A, et al. First multi-center all-comers study for the aquablation procedure. J Clin Med. 2020 Feb 24;9(2):603.

Bates AS, Ayers J, Kostakopoulos N, et al. A systematic review of focal ablative therapy for clinically localized prostate cancer in comparison with standard management options: limitations of the available evidence and recommendations for clinical practice and further research. Eur Urol Oncol. 2021 Jan 8: S2588-9311(20)30216-9.

Bertolo R, Iacovelli V, Cipriani C, et al. Ejaculatory function following transperineal laser ablation vs TURP for benign prostatic obstruction: a randomized trial. BJU Int. 2023 Jul;132(1):100-108.

Bhatia S, Sinha VK, Kava BR, et al. Efficacy of prostatic artery embolization for catheter-dependent patients with large prostate sizes and high comorbidity scores. J Vasc Interv Radiol. 2018 Jan;29(1):78-84.e1. Epub 2017 Nov 15.

Bhojani N, Bidair M, Zorn KC, et al. Aquablation for benign prostatic hyperplasia in large prostates (80-150 cc): 1-year results. Urology. 2019 Jul;129:1-7.

Canat HL, Gurbuz C, Bozkurt M. Transurethral resection of the prostate (TURP) versus transperineal laser ablation (TPLA) due to benign prostatic hyperplasia (BPH): prospective and comparative study. Int Urol Nephrol. 2023 Nov;55(11):2747-2752.

Chin JL, Billia M, Relle J, et al. Magnetic resonance imaging-guided transurethral ultrasound ablation of prostate tissue in patients with localized prostate cancer: a prospective phase 1 clinical trial. Eur Urol. 2016 Sep;70(3):447-55.

Chin YF and Lynn N. Systematic review of focal and salvage cryotherapy for prostate cancer. Cureus. 2022 Jun 28;14(6):e26400.

Chughtai B, Elterman D, Shore N, et al. The iTind temporarily implanted nitinol device for the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia: a multicenter, randomized, controlled trial. Urology. 2020 Dec 26:S0090-4295(20)31520-X.

Davis, JW, Chang, DW, Chevray, P, et al. Randomized phase II trial evaluation of erectile function after attempted unilateral cavernous nerve-sparing retropubic radical prostatectomy with versus without unilateral sural nerve grafting for clinically localized prostate cancer. Eur Urol. 2009;55(5):1135-1143.

de Rienzo G, Lorusso A, Minafra P, et al. Transperineal interstitial laser ablation of the prostate, a novel option for minimally invasive treatment of benign prostatic obstruction. Eur Urol. 2021 Jul;80(1):95-103.

Desai M, Bidair M, Bhojani N, et al. Aquablation for benign prostatic hyperplasia in large prostates (80-150 cc): 2-year results. Can J Urol. 2020 Apr;27(2):10147-10153.

Dineen MK, Shore ND, Lumerman JH, et al. Use of a temporary prostatic stent after transurethral microwave thermotherapy reduced voiding symptoms and bother without exacerbating irritative symptoms. Urology. 2008 May;71(5):873-7.

ECRI Institute. UroLift System (NeoTract, Inc.) for Treating Benign Prostatic Hyperplasia. Plymouth Meeting (PA): ECRI Institute; 2019 Jul 01. (Custom Product Brief).

ECRI. AquaBeam Robotic System (Procept BioRobotics Corp.) for treating benign prostatic hyperplasia. Clinical Evidence Assessment. 2023 Sep.

ECRI. Irreversible electroporation for treating prostate cancer. Evidence Analysis. 2025 Feb.

ECRI. iTind System (Olympus America, Inc.) for treating benign prostatic hyperplasia. Clinical Evidence Assessment. 2023 Mar.

ECRI. Optilume BPH Catheter System (Laborie Medical Technologies Corp.) for treating benign prostatic hyperplasia. Clinical Evidence Assessment. 2024 Aug.

ECRI. Transperineal laser ablation for treating benign prostatic hyperplasia. Evidence Analysis. 2025 Sept.

Elterman D, Gilling P, Roehrborn C, et al. Meta-analysis with individual data of functional outcomes following aquablation for lower urinary tract symptoms due to BPH in various prostate anatomies. BMJ Surg Interv Health Technol. 2021 Jun 23.

European Association of Urology (EAU). Guidelines on non-neurogenic male lower urinary tract symptoms (LUTS), incl. benign prostatic obstruction (BPO). 2023. Available at: https://uroweb.org/guidelines. Accessed October 29, 2025.

Gabr AH, Gabr MF, Elmohamady BN, et al. Prostatic artery embolization: a promising technique in the treatment of high-risk patients with benign prostatic hyperplasia. Urol Int. 2016;97(3):320-324.

George AK, Miocinovic R, Patel AR, et al. Irreversible electroporation for prostate tissue ablation in patients with intermediate-risk prostate cancer: results from the PRESERVE trial. Eur Urol. 2025 Jul 19:S0302-2838(25)00346-X.

Gilling P, Anderson P, Tan A. Aquablation of the prostate for symptomatic benign prostatic hyperplasia: 1-year results. J Urol. 2017 Jun;197(6):1565-1572.

Gilling P, Barber N, Bidair M, et al. Three-year outcomes after aquablation therapy compared to TURP: results from a blinded randomized trial. Can J Urol. 2020 Feb;27(1):10072-10079.

Gilling PJ, Barber N, Bidair M, et al. Five-year outcomes for aquablation therapy compared to TURP: results from a double-blind, randomized trial in men with LUTS due to BPH. Can J Urol. 2022 Feb;29(1):10960-10968.

Gilling PJ, Barber N, Bidair M, et al. Randomized controlled trial of aquablation versus transurethral resection of the prostate in benign prostatic hyperplasia: one-year outcomes. Urology. 2019; 125:169-173.

Gratzke C, Barber N, Speakman MJ, et al. Prostatic urethral lift vs transurethral resection of the prostate: 2-year results of the BPH 6 prospective, multicenter, randomized study. BJU Int 2017 May;119(5):767-775.

Harke NN, Strauss S, Peters I, et al. Spider silk erectile nerve reconstruction in robot-assisted radical prostatectomy: a first-in-men feasibility analysis. World J Urol. 2023 May 17:1–7.

Hayes, Inc. Aquablation for treatment of benign prostatic hyperplasia. Lansdale, PA: Hayes, Inc.; March 30, 2021; amended April 2021. Annual review March 2024.

Hayes, Inc. Evolving Evidence Review. iTind (Olympus) for benign prostatic hyperplasia. Lansdale, PA: Hayes Inc.; March 2022. Annual review September 2025.

Hayes, Inc. Evolving Evidence Review. NanoKnife System (AngioDynamics Inc.) for Treatment of Localized Prostate Cancer. Lansdale, PA: Hayes Inc.; May 14, 2025.

Hayes, Inc. Health Technology Assessment. Prostatic artery embolization for treatment of benign prostatic hyperplasia. April 2023. Annual review May 2025.

Hayes, Inc. Health Technology Assessment. Prostatic urethral lift (UroLift System) for treatment of symptoms associated with benign prostatic hyperplasia. Lansdale, PA: Hayes Inc.; June 2020; amended August 2021. Annual review June 2023.

Hopstaken JS, Bomers JGR, Sedelaar MJP, et al. An updated systematic review on focal therapy in localized prostate cancer: what has changed over the past 5 years? Eur Urol. 2022 Jan;81(1):5-33.

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(2):CD013143. Published 2019 Feb 13.

Iacovelli V, Carilli M, Bertolo R, et al. Transperineal laser ablation for focal therapy of localized prostate cancer: 12-month follow-up outcomes from a single prospective cohort Study. Cancers (Basel). 2024 Jul 23;16(15):2620.

Johannsen M, Gneveckow U, Taymoorian K, et al. Morbidity and quality of life during thermotherapy using magnetic nanoparticles in locally recurrent prostate cancer: results of a prospective phase I trial. Int J Hyperthermia. 2007 May;23(3):315-23.

Jordan GH, Wessells H, Secrest C, et al. United States Study Group. Effect of a temporary thermo-expandable stent on urethral patency after dilation or internal urethrotomy for recurrent bulbar urethral stricture: results from a 1-year randomized trial. J Urol. 2013 Jul;190(1):130-6.

Jung JH, McCutcheon KA, Borofsky M, et al. Prostatic arterial embolization for the treatment of lower urinary tract symptoms in men with benign prostatic hyperplasia. Cochrane Database Syst Rev. 2022 Mar 29;3(3):CD012867.

Jung JH, Risk MC, Goldfarb R, et al. Primary cryotherapy for localised or locally advanced prostate cancer. Cochrane Database Syst Rev. 2018 May 30;5(5):CD005010.

Kaplan SA, Moss J, Freedman S, 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.

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 Sep;27(3):531-536.

Kaplan SA, Pichardo M, Rijo E, et al. Long-term outcomes after treatment with Optilume BPH Four-year results from the EVEREST study. Can Urol Assoc J. 2024 Nov;18(11):E319-E325.

Kaplan SA, Pichardo M, Rijo E, et al. One-year outcomes after treatment with a drug-coated balloon catheter system for lower urinary tract symptoms related to benign prostatic hyperplasia. Prostate Cancer Prostatic Dis. 2021 Dec;24(4):1073-1079.

Kernen KM, Omar S, Goodnight B, et al. 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.

Kim KS, Choi S, Choi YS, et al. Comparison of efficacy and safety between a segmental thermos-expandable metal alloy spiral stent (Memokath 051) and a self-expandable covered metallic stent (UVENTA) in the management of ureteral obstructions. J Laparoendosc Adv Surg Tech. 2014; 24(8):550-5.

Klotz L, Pavlovich CP, Chin J, et al. Magnetic resonance imaging-guided transurethral ultrasound ablation of prostate cancer. J Urol. 2021 Mar;205(3):769-779.

Kung TA, Waljee JF, Curtin CM, et al. Interpositional nerve grafting of the prostatic plexus after radical prostatectomy. Plast Reconstr Surg Glob Open. 2015 Aug 10;3(7): e452.

Kuwata, Y, Muneuchi, G, Igawa HH, et al. Dissociation of sexual function and sexual bother following autologous sural nerve grafting during radical prostatectomy. Int J Urol. 2007;14(6):510-514.

Manenti G, Perretta T, Nezzo M, et al. Transperineal laser ablation (TPLA) treatment of focal low-intermediate risk prostate cancer. Cancers (Basel). 2024 Apr 3;16(7):1404.

McWilliams JP, Bilhim TA, Carnevale FC, et al. Society of Interventional Radiology Multi-society 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.

Nair SM, Hatiboglu G, Relle J, et al. Magnetic resonance imaging-guided transurethral ultrasound ablation in patients with localised prostate cancer: 3-year outcomes of a prospective phase I study. BJU Int. 2021 May;127(5):544-552.

Namiki S, Saito S, Nakagawa H, et al. Impact of unilateral sural nerve graft on recovery of potency and continence following radical prostatectomy: 3-year longitudinal study. J Urol. 2007 Jul;178(1):212-6; discussion 216.

National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology. Prostate cancer v3.2026. November 7, 2025.

National Institute for Health and Care Excellence (NICE). Interventional procedures guidance [IPG770]. Transurethral water-jet ablation for lower urinary tract symptoms caused by benign prostatic hyperplasia. September 2023.

National Institute for Health and Care Excellence (NICE). Interventional procedures guidance [IPG611]. Prostate artery embolization for lower urinary tract symptoms caused by benign prostatic hyperplasia. April 2018.

National Institute for Health and Care Excellence (NICE). Interventional procedures guidance [IPG423]. Focal therapy using cryoablation for localised prostate cancer. April 2012.

National Institute for Health and Care Excellence (NICE). Medical technologies guidance [MTG49]. Rezum for treating lower urinary tract symptoms secondary to benign prostatic hyperplasia. June 2020.

Ottaiano N, Shelton T, Sanekommu G, et al. Surgical complications in the management of benign prostatic hyperplasia treatment. Curr Urol Rep. 2022 May;23(5):83-92. Epub 2022 Mar 9.

Pacella CM, Patelli G, Iapicca G, et al. Transperineal laser ablation for percutaneous treatment of benign prostatic hyperplasia: a feasibility study. Results at 6 and 12 months from a retrospective multi-centric study. Prostate Cancer Prostatic Dis. 2020 Jun;23(2):356-363.

Pacini M, Zucchi A, Salonia A, et al. Short term results after minimally invasive treatments for benign prostatic enlargement: the first randomized trial comparing transperineal laser ablation and water vapor ablation. Prostate Cancer Prostatic Dis. 2025 Dec;28(4):978-984.

Peters I, Hensen B, Glandorf J, et al. First experiences using transurethral ultrasound ablation (TULSA) as a promising focal approach to treat localized prostate cancer: a monocentric study. BMC Urol. 2023 Aug 29;23(1):142.

Pimentel MA, Yassaie O, Gilling P. Urodynamic outcomes after aquablation. Urology. 2019 Apr; 126:165-170.

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 Mar;77(3):354-362.

Plante M, Gilling P, Barber N, et al. Symptom relief and anejaculation after aquablation or transurethral resection of the prostate: subgroup analysis from a blinded randomized trial. BJU Int. 2018.

Polverino P, Lo Re M, Moscardi L, et al. Transperineal focal laser ablation of the prostate for prostate cancer: a systematic review of the literature. Cancers (Basel). 2025 Mar 13;17(6):968.

Rampoldi A, Barbosa F, Secco S, et al. Prostatic artery embolization as an alternative to indwelling bladder catheterization to manage benign prostatic hyperplasia in poor surgical candidates. Cardiovasc Intervent Radiol. 2017 Apr;40(4):530-536.

Reale G, Cimino S, Bruno G, et al. "Aquabeam® System" for benign prostatic hyperplasia and LUTS: birth of a new era. A systematic review of functional and sexual outcome and adverse events of the technique. Int J Impot Res. 2019;31(6):392-399.

Reece JC, Dangerfield DC, Cooms C. End-to-side somatic-to-autonomic nerve grafting to restore erectile function and improve quality of life after radical prostatectomy. Eur Urol. 2019 Aug;76(2):189-196.

Roehrborn CG, Barkin J, Gange SN, et al. Five-year results of the prospective randomized controlled prostatic urethral L.I.F.T. study. Can J Urol . 2017 Jun;24(3):8802-8813.

Saito S, Namiki S, Numahata K, et al. Impact of unilateral interposition sural nerve graft on the recovery of sexual function after radical prostatectomy in Japanese men: a preliminary study. Int J Urol. 2007;14(2):133-139.

Sajan A, Mehta T, Desai P, et al. Minimally invasive treatments for benign prostatic hyperplasia: systematic review and network meta-analysis. J Vasc Interv Radiol. 2022 Apr;33(4):359-367.e8.

Sandhu JS, Bixler BR, Dahm P, et al. Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia (BPH): AUA Guideline amendment 2023. J Urol. 2023;10.1097/JU.0000000000003698.

Sengupta S and Balla VK. A review on the use of magnetic fields and ultrasound for non-invasive cancer treatment. J Adv Res. 2018 Jun 20;14:97-111.

Shauly O, Gould DJ, Patel KM. Emerging nonsurgical and surgical techniques to treat erectile dysfunction: a systematic review of treatment options and published outcomes. J Plast Reconstr Aesthet Surg. 2019 Apr;72(4):532-538.

Shore ND, Dineen MK, Saslawsky MJ, et al. A temporary intraurethral prostatic stent relieves prostatic obstruction following transurethral microwave thermotherapy. J Urol. 2007 Mar;177(3):1040-6.

Siddiqui KM, Billia M, Mazzola CR. Three-year outcomes of recovery of erectile function after open radical prostatectomy with sural nerve grafting. J Sex Med. 2014 Aug;11(8):2119-24.

Souza Trindade JC, Vitrbo F, Petean Trindade A, et al. Long-term follow-up of treatment of erectile dysfunction after radical prostatectomy using nerve grafts and end-to-side somatic-autonomic neurorraphy: a new technique. BJU Int. 2017;119(6):948-954.

Sugimoto, M, Tsunemori H, Kakehi Y. Health-related quality of life evaluation in patients undergoing cavernous nerve reconstruction during radical prostatectomy. Jpn J Clin Oncol. 2009;39(10):671-676.

Tafuri A, Panunzio A, De Carlo F, et al. Transperineal laser ablation for benign prostatic enlargement: a systematic review and pooled analysis of pilot studies. J Clin Med. 2023 Feb 26;12(5):1860.

Tapping CR, Macdonald A, Hadi M, et al. Prostatic artery embolization (PAE) for benign prostatic hyperplasia (BPH) with haematuria in the absence of an upper urinary tract pathology. Cardiovasc Intervent Radiol. 2018 Aug;41(8):1160-1164.

Tian W, Zhou C, Leng B, et al. Prostatic artery embolization for control of gross hematuria in patients with benign prostatic hyperplasia: a single-center retrospective study in 20 patients. J Vasc Interv Radiol. 2019 May;30(5):661-667.

Tricard T, Cazzato RL, Schroeder A, et al. Magnetic resonance imaging-guided transurethral ultrasound ablation (TULSA) of localized prostate cancer: a prospective trial. J Vasc Interv Radiol. 2025 Sep;36(9):1401-1408.

Valerio M, Cerantola Y, Eggener SE, et al. New and established technology in focal ablation of the prostate: a systematic review. Eur Urol. 2017 Jan;71(1):17-34.

Veyg D, Mohanka R, Rumball IP, et al. Comparison of 24-month clinical outcomes after prostatic artery embolization in prostate glands larger versus smaller than 80 mL: a systematic review. J Vasc Interv Radiol. 2023 Apr;34(4):578-584.e1.

Xiang P, Guan D, Du Z, et al. Efficacy and safety of prostatic artery embolization for benign prostatic hyperplasia: a systematic review and meta-analysis of randomized controlled trials. Eur Radiol. 2021 Jan 15.

Xu C, Zhang G, Wang JJ, et al. Safety and efficacy of prostatic artery embolization for large benign prostatic hyperplasia in elderly patients. J Int Med Res. 2021 Jan;49(1):300060520986284.

Zucchi A, Bartoletti R, Antonov P, et al. Preserving erectile and ejaculatory function in patients undergoing minimally invasive techniques: the first randomized clinical trial comparing convective water vapor ablation and transperineal laser ablation. J Sex Med. 2025 Aug 4;22(8):1447-1454.

Zumstein V, Betschart P, Vetterlein MW, et al. 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.

Policy History/Revision Information

Date	Summary of Changes
06/01/2026	**Coverage Rationale** ***Prostatic Urethral Lift*** • Replaced language indicating "prostatic urethral lift (PUL) is proven and medically necessary when performed according to the [listed] U.S. Food and Drug Administration labeled indications, contraindications, warnings, and precautions" with "prostatic urethral lift is proven and medically necessary *for treating urinary symptoms caused by benign prostatic hyperplasia (BPH)* when performed according to the [listed] U.S. Food and Drug Administration labeled indications, contraindications, warnings, and precautions" • Revised list of U.S. Food and Drug Administration labeled indications for prostatic urethral lift: o Replaced "treating symptoms due to urinary outflow obstruction secondary to BPH, including lateral, *with or without* median lobe hyperplasia, in men 45 years of age or older" with "treating symptoms due to urinary outflow obstruction secondary to BPH, including lateral *and* median lobe hyperplasia, in men 45 years of age or older" o Added notation to indicate lobe hyperplasia can be either lateral or median ***Transurethral Water Jet Ablation*** • Replaced language indicating "transurethral water jet ablation for the treatment of *malignant* prostate *tissue* and all other indications [not listed in the policy as proven and medically necessary] is unproven and not medically necessary" with "transurethral water jet ablation for the treatment of prostate *cancer (in individuals who do not meet the [listed] criteria)* and all other indications [not listed in the policy as proven and medically necessary] is unproven and not medically necessary" ***Prostate Artery Embolization*** • Revised list of proven and medically necessary indications for prostate artery embolization:

Date	Summary of Changes
	○ Added: ▪ Individuals with lower urinary tract symptoms attributable to BPH, as confirmed by a board-certified urologist, with failure of conservative therapy (α-blockers and/or 5-α reductase inhibitors) and any of the following: – Significant comorbidities (e.g., American Society of Anesthesiologists Physical Status Classification of class III or higher) – Presence of coagulopathy – Inability to stop anticoagulation or platelet therapy – A prostate volume of > 80 g confirmed by imaging (transrectal ultrasound, magnetic resonance imaging, or computed tomography) ○ Removed "individuals with BPH who are ineligible for other procedures due to surgical constraints (i.e., prostate size) or anesthesia risk (i.e., comorbidities)" ***Other Procedures*** • Revised list of unproven and not medically necessary indications; added: ○ Irreversible electroporation ablation ○ Autologous (e.g., sural) or allogeneic nerve grafts to restore erectile function during or after radical prostatectomy **Medical Records Documentation Used for Reviews** • Updated list of Medical Records Documentation Used for Reviews; added: ○ Comorbidities using a validated scale (e.g., American Society of Anesthesiologists Physical Status Classification) ○ For prostatic urethral lift, in addition to the [listed required documentation], also include urethra conditions that may prevent insertion of delivery system into the bladder ○ For prostate artery embolization, in addition to the [listed required documentation], also include lower urinary tract symptoms attributable to BPH, as confirmed by a board-certified urologist **Definitions** • Added definition of "American Society of Anesthesiologists (ASA) Physical Status Classification System" **Applicable Codes** • Added CPT codes 55877, 55899, and 64999 **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information • Archived previous policy version 2026T0618O and 2026T0372BB

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.