Prostate Surgeries and Interventions (for Nebraska Only)

Policy Number: CS334NE.H
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Instructions for Use

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Related Policies

None

Application

This Medical Policy only applies to the State of Nebraska.

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 (PUL) is proven and medically necessary when performed according to the following U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings, and precautions:

- Treating symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH), including lateral, with or without 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 bladder
- Urinary incontinence due to incompetent sphincter
- Current gross hematuria

Prostatic urethral lift (PUL) 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 benign prostatic hyperplasia (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 (LUTS) due to benign prostatic hyperplasia.

Transurethral water jet ablation 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.

Prostate Artery Embolization (PAE)

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

- Individuals with BPH who are ineligible for other procedures due to surgical constraints (i.e., prostate size) or anesthesia risk (i.e., comorbidities)
- Persistent gross hematuria originating from the prostate

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)

Medical Records Documentation Used for Reviews

Benefit coverage for health services is determined by the federal, state, or contractual requirements, 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.

The patient's medical record must contain documentation that fully supports the medical necessity for the requested services. This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures. Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and must be made available upon request.

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 federal, state, or contractual requirements 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
0421T	Transurethral waterjet ablation of prostate, including control of post-operative bleeding, including ultrasound guidance, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included when performed)
0582T	Transurethral ablation of malignant prostate tissue by high-energy water vapor thermotherapy, including intraoperative imaging and needle guidance
0619T	Cystourethroscopy with transurethral anterior prostate commissurotomy and drug delivery, including transrectal ultrasound and fluoroscopy, when performed
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
52442	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; each additional permanent adjustable transprostatic implant (List separately in addition to code for primary procedure)
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)
55881	Ablation of prostate tissue, transurethral, using thermal ultrasound, including magnetic resonance imaging guidance for, and monitoring of, tissue ablation;

CPT Code	Description
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

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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 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 (TPLA) 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 patient'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 (FLA) 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 (PUL) 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 which widens the urethra 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 anti-proliferative agent coated (paclitaxel) dilation system. It is intended to maintain luminal patency of the prostatic urethra after dilation (Kaplan 2023).

Transurethral ultrasound ablation (TULSA) is a novel focal approach to treating localized prostate cancer in which a rotating ultrasound probe is placed in the prostatic urethra to apply heat to ablate the prostate tissue. Real-time MRI-thermometry assures monitoring of heat development during the procedure (Peters 2023).

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 not possible. Twenty-six studies in total were included, with single arm case series and

double arm retrospective studies comprised of 11,228 patients. Eleven studies were for patients receiving cryotherapy for recurrent cancer, and fifteen were for the primary treatment for newly diagnosed cancer. In the eleven primary treatment studies, the results of ten showed 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 53-69%. Six studies reported 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 ASTRO Phoenix definition, whereas two studies reviewed the rate of positive post-procedural prostate biopsy. The recurrence rate ranged 15.4% to 40.3% and 18% to 62% respectively. 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. For the studies that focused on salvage therapy, for oncological outcomes, six studies reported the cancer-specific survival rate from 65.5% to 100.0%, two studies showed the range of biochemical-free survival from 48.1% to 58.1%, and one study reported an ADT-free survival rate of 71.3%. Three studies described an overall survival rate of 92.0%-99.1%, and two studies reported a median survival rate of 11.8-12.3 years. In five studies the post-therapy 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 13-74 months. 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 require interpreting the results with caution. This review is limited by the heterogeneity of 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 patients with localized prostate cancer. A PubMed, Embase, and The Cochrane Library were searched for studies between October 2015 and December 31, 2020. Seventy-two studies were found which included the following: twenty seven studies on high-intensity focused ultrasound (HIFU), nine studies on irreversible electroporation, eleven on cryoablation, eight on focal laser ablation and focal brachytherapy, seven on photodynamic therapy (PDT), two on radiofrequency ablation, and one on prostatic artery embolization. Of the eleven studies on cryoablation, six were retrospective studies, one of which compared HIFU with cryoablation, and five were prospective studies. No randomized controlled trials (RCT) were identified for cryotherapy. The authors concluded 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 its 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 to standard treatment options for primary treatment of localized or locally advanced prostate cancer. A search was conducted using multiple databases (CENTRAL, MEDLINE, EMBASE), clinical trial registries and a grey literature repository (Grey Literature Report). The search resulted in two RCTs which included 307 men that were randomized into either a group for cryotherapy or radiation. The authors found uncertainty with regards to the effects of freezing the prostate when compared to 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 (PUL)

A 2020 Hayes health technology assessment (updated in 2023) regarding the UroLift System for treating symptoms associated with BPH states that a fair to low-quality body of noncomparative evidence suggests that PUL with the UroLift System may improve LUTS 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 TURP, and the limited long-term evidence regarding the durability and safety of this device.

In 2017, Roehrborn et al. published five-year outcomes of the prospective, multi-center, randomized, blinded sham control trial of the PUL in participants with bothersome lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH). In this nineteen-center study, two hundred and six participants ≥ 50 years old with an International Prostate Symptom Score (IPSS) > 12, peak flow rate (Qmax) ≤ 12 mL/s, and prostate volume 30 cc-80 cc were randomized 2:1 to the PUL procedure or blinded sham control. IPSS improvement after PUL was 88% greater than that of sham at three months. LUTS and QOL were significantly improved by 2 weeks with return to preoperative physical activity within 8.6 days. Improvement in international prostate symptom score (IPSS), QOL, BPH Impact Index (BPHII), and maximum flow rate (Qmax) were durable through five years with improvements of 36%, 50%, 52%, and 44% respectively. Symptom improvement was commensurate with patient satisfaction. The authors conclude that PUL offers a durable, minimally invasive option in the treatment of LUTS due to BPH.

Two-year outcomes were reported by Gratzke et al. (2017) for the BPH6 prospective, multicenter, non-blinded randomized study (n = 80) which compared PUL to TURP. Inclusion criteria were individuals aged ≥ 50 years and a candidate for TURP, with IPSS > 12, maximum urinary flow rate (Q max) ≤ 15 mL/s, and prostate volume ≤ 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 month, 3 months, 6 months, 1 year and 2 years. Significant improvements in IPSS, IPSS QoL, BPHII and Qmax were observed in both arms through 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 Q max at all time points. HRQoL and BPHII improvements were not statistically different. Quality of recovery, as defined by at least a score of 70 on the QoR VAS (0-100 scale), was superior for PUL compared with TURP, with 82% of patients in the PUL arm achieving the recovery endpoint by 1 month compared with 53% of patients in the TURP arm (p = 0.008). The results demonstrate that both the PUL and TURP procedures offered significant improvement in symptoms, Q max and HRQoL. The modest patient number may not have provided sufficient statistical power to detect differences in some of the secondary outcome variables.

Transurethral Waterjet Ablation (Aquablation)

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 to that of TURP, the gold standard for BPH. One hundred and eighty one participants aged 45-80 with BPH were randomized into either receiving aquablation or the control group (TURP). The aquablation was performed using the AquaBeam Robotic System. The participants were followed for five years and staff performing assessments were blinded for three years; years four and five occurred during the COVID-19 pandemic. The primary efficacy endpoint was the change in IPPS from baseline to six months and was successfully achieved; at six 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 five years, the median IPSS score was 5.5 for the aquablation group and 6 for the TURP group. The MSHQ-EjD-SF (MSHQ-EjD) score averaged 2.7 points lower (or worse) for the TURP group compared to the aquablation group. After five years, the 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 the health outcomes from aquablation therapy outweigh those when compared to a TURP, and at five years, uroflow improvement continues to show durability and consistency. Limitations included the loss to follow up rate at years four and five and the sole funding of the study came from the device manufacturer.

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

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

Gilling et al. (2020) reported the results of participants from the Water I clinical trial to report 3-year outcomes for aquablation compared to TURP for the treatment of LUTS related to BPH. Assessments included IPAA, MSHQ-EjD, 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 -3.3-2.2, p = .6848). Similarly, 3-year improvements in Qmax were 11.6 and 8.2 cc/sec [difference of 3.3 (95% CI -0.5-7.1) cc/sec, p = .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 three-year BPH symptom reduction and urinary flow rate improvement were similar after TURP and aquablation therapy. No subjects required surgical retreatment beyond 20 months postoperatively. 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 three years, as it was powered for non-inferiority at six 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 80-150 cc in a prospective, multicenter international case series (WATER II). Participants had a mean prostate volume of 107 cc and the results showed IPSS and IPSS quality of life 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 timeframe, all but 2 of the 74 participants stopped taking alpha blockers and all but 32 stopped taking 5α-reducatase inhibitors. During the 2-year study time frame, adverse urological events were low and included 2 subjects with recurrent BPH symptoms that required retreatment with TURP and HOLEP. The authors concluded that the aquablation procedure is a safe and effective treatment for men with LUTS due to BPH with larger prostate volumes and 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 LUTS due to BPH in 177 participants enrolled at five treatment centers between September 2017 and December 2018. The primary endpoint was the change in total IPSS from baseline to 3 months. Secondary endpoints included the following: (1) Proportion of participants who were sexually active at the baseline and experienced either ejaculatory or erectile dysfunction at 3 months, change from the baseline to 3 months in maximal flow rate (Qmax), prostate specific antigen (PSA) level, post-void 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. Inclusion criteria was a diagnosis of LUTS due to BPH and a prostate size between 20 and 150 cc. Exclusion criteria included being unable to stop anticoagulants and antiplatelet agents perioperatively or had a bleeding disorder, had a history of gross hematuria, were using systemic immune suppressants, had a contraindication to both general and spinal anesthesia, were unwilling to accept transfusion if required, or had any severe illness that could prevent complete follow-up. At baseline and 3 and 12 month follow up, participants completed the International Prostate Symptom Score (IPSS), Incontinence Severity Index, Pain Intensity Scale, Quality of Recovery Visual Analog Scale, International Index of Erectile Function (IIEF-15), the Male Sexual Health Questionnaire (MSHQ-EjD), uroflowmetry and post void residual volume (PVR) measurements. The results showed of the original 177 participants 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 3-month follow-up, and 6.4 (4.8) at 12-month follow-up. IPSS QOL scores improved from 4.7 (1.1) at baseline to 1.5 (1.4) at 3-month follow-up, and 1.4 (1.4) at 12-month follow-up. IPSS storage and voiding scales also improved significantly ($p < 0.0001$) at 3 and 12 months. 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. Postvoid residual improved from 108 (108) to 47 (77) cc at three months and 61 (74) cc at 12 months. Of the 92 men that 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. 141 participants had transrectal ultrasound 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 ISI improved non-significantly. Dysuria of any frequency was reported by 51% at baseline and 29% at 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 3 month follow up. 82 of the participants were taking medication for BPH preoperatively and by month 3, all but 8 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 LUTS due to BPH and replicate results previously seen in a trial setting. This study is limited by a lack of a concurrent control group and a 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, the Gilling 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 quality of life may also be similar (low-certainty evidence). There is uncertainty whether patients undergoing aquablation are at higher or lower risk for major adverse events (very low-certainty evidence). Aquablation may result in little to no difference in erectile function but 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 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 LUTS 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 LUTS related to BPH. A total of 181 participants with BPH were randomly assigned (2:1 ratio) to either aquablation or TURP. Participants and

follow-up assessors were blinded to treatment. Assessments included the IPSS, MSHQ, IIEF and uroflow. At 2 years, IPSS scores improved by 14.7 points in the aquablation group and 14.9 points in TURP (p = 0.8, 95% CI: -2.1 to 2.6 points). Two-year improvements in Qmax were 11.2 and 8.6 cc/s for aquablation and TURP, respectively (p = 0.2, 95% CI: -1.3 to 6.4). Sexual function as assessed by 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 re-treatment 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 2-year efficacy outcomes after TURP and aquablation were similar, and the rate of surgical re-treatment was low and similar to TURP; aquablation may be an alternative for men who strongly prefer maintenance of ejaculatory function. The sample size may however 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, IPSS, PVR), sexual outcome (erectile dysfunction and anejaculation rate), and adverse events evaluated according to the Clavien-Dindo classification. The functional outcomes, evaluated after water jet dissection, have shown improvement with respect to the baseline in all the selected articles. In the comparison papers with the TURP, the aquablation has been statistically not inferior regarding functional outcomes. The sexual outcomes have 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, were not statistically superior to 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 mean baseline pDet@qmax was 71 and 73 cm H20 in the aquablation and TURP groups, respectively. At 6-month follow-up, pDet@qmax decreased by 35 and 34 cm H20, respectively. A large negative shift in bladder outlet obstruction index was observed, consistent with a large reduction in the proportion of individuals with obstruction at follow-up compared to 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 reports that based on evidence from one RCT and four systematic reviews, aquablation is safe and reduces BPH-related LUTS for up to five years in patients with prostates between 80 and 150 mL. Systematic reviews reported that aquablation works as well or better than UroLift, Rēzum, iTIND, and prostatic artery embolization (PAE), but these comparisons are indirect and firm conclusions cannot be drawn. Studies also show outcomes as well as or better than TURP, and fewer patients required retreatment at 5 year follow up. Additional studies are needed that compare AquaBeam to other minimally invasive treatments for LUTS due to BPH.

Plante et al. (2018, included in Hayes health technology assessment, and ECRI clinical evidence assessment) conducted prespecified post hoc exploratory subgroup analyses from a double-blind, multicenter prospective randomized controlled trial that compared TURP using either standard electrocautery vs. surgery using robotic waterjet (aquablation) to determine whether certain baseline factors predicted more marked responses after aquablation as compared with TURP. The primary efficacy endpoint was reduction in International Prostate Symptom Score (IPSS) at 6 months. The primary safety endpoint 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, a larger difference than the overall result. The primary safety endpoint difference was greater for individuals with 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. 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 post-void residual urine volume. The authors concluded that in individuals with moderate-to-severe lower urinary tract symptoms 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 patients with a prostate size 30 to 80 cc. Therefore, results may not be generalizable for all prostate sizes.

Gilling et al. (2017, included in Hayes Health Technology Assessment) performed a prospective, single arm, multicenter trial at a total of 3 centers in Australia and New Zealand with 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 benign prostatic hyperplasia. A total of 21 individuals with moderate to severe lower urinary tract symptoms (LUTS) were included in the study with in-clinic follow up visits at 1, 3, 6, and 12 months. The visits included a review of AEs, uroflow measurements prostate specific antigen (PSA) measurement (at 6 and 12 months only), completion of study questionnaires, and (at 6 months only) urodynamics and transrectal ultrasound (TRUS). Symptoms related to LUTS had significantly improved from baseline at 1 month and were sustained through month 12. At 12 months, the mean international prostatic symptom score (I-PSS) score had improved by 16.2 points. The I-PSS 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 post-void residual volume (PVR) 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 a month 6. Mean serum PSA, which was measured in 20 subjects, 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 postoperatively. The authors concluded that this study provides early evidence to support the safety and effectiveness of aquablation for symptomatic benign prostatic hyperplasia by improved symptom scores and other measures of obstruction. The study is of small sample size and lacks 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 (PAE)

There is insufficient evidence to assess the efficacy of PAE relative to laser enucleation of the prostate or prostate urethral lift. Additional randomized controlled trials (RCTs) with > 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, particularly in male persons who are poor candidates for TURP due to frailty or comorbidities. PAE may however be indicated for some individuals who are not eligible for established surgeries or for persistent gross hematuria originating from the prostate.

In 2023, Hayes conducted a health technology assessment regarding prostatic artery embolization compared to open prostatectomy and minimally invasive procedures for moderate to severe BPH. 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.

In a 2023 systematic review, Veyg et al. compared the 24-month outcomes following PAE for symptomatic BPH in patients with prostatic volume (PV) > 80 mL with those with a volume of < 80 mL. A total of 14 studies with 2,260 patients were included. Ten studies included PV greater than 80 mL, and 4 included PV less than 80 mL. Preoperatively, the mean PV was 110.1 mL, and the mean IPSS, Post Void Residual (PVR), and Qmax were 22.6, 126.9 mL and 8.3 mL/s respectively. The mean pre-procedure 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 24 month follow up, the results showed a mean IPSS of 8.4. Other outcomes were not consistently reported among all of the studies. Ten studies reported PVR of 58.5, 9 reported Qmax score of 14.7, 7 studies reported IIEF-5 scores of 13.1. 12 studies measured PSA and showed a mean value of 3.6ng/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 patients 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 a Cochrane review, Jung et al. (2022) completed a systematic review of literature to assess the effects of PAE compared to other procedures for treatment of lower urinary tract symptoms in men diagnosed with benign prostatic hypertrophy. The authors focused on PAE versus transurethral resection of the prostate (TURP) which included six RCTs and two non-randomized studies (NRSs) evaluating short-term follow-up, and two RCTs and one NRS evaluating long-term follow-up. The evidence suggests that PAE may provide similar improvement in urologic symptom scores and quality of life when compared to TURP, but there is high uncertainty regarding major adverse events and PAE likely increases retreatment rates. While erectile function was similar for both groups, PAE may reduce ejaculatory disorders. The authors noted that the certainty of evidence for the outcomes measured in this review was low or very low except for retreatment which was moderate-certainty evidence indicating that confidence in the reported effect size is limited to very limited and should be better informed by future research.

Sajan et al. (2022) conducted a systematic review and network analysis on the outcomes of minimally invasive therapies for LUTS secondary to BPH. Nine studies were included which contained 1,034 participants. The following comparisons were identified: Four studies focused on PAE versus TURP and then the following individual studies: PAE versus sham,

UroLift versus TURP, UroLift versus sham, Rezum versus Sham, and aquablation versus TURP. Data for IPSS, QoL, QMax, PVR, and prostate volume were all obtained presurgical for baseline values and then again at 3-, 6-, and 12-months; primary outcome measured was the IPSS scores. Four RCTs compared PAE to TURP and one RCT compared PAE versus sham. No major IPSS differences were noted but for PAE, the IPSS mean difference was one of the lowest at 12 months. No significant differences were found in Qmax, QoL, and PVR. The sham group (Rezum vs. sham, UroLift vs. sham and PAE vs. sham) found significant differences favoring the TURP for Qmax, PVR, and QoL with no other substantial differences noted. The authors found the main strength of PAE were the 5 RCTs studies with four direct comparisons to TURP and the findings of lower in hospital costs. The disadvantages were a longer procedural time, exposure to radiation and potential for nontarget embolization. The authors concluded there were clinical benefits for PAE with minimal adverse effects. The analysis is limited by the indirectness of network meta-analyses and inclusions of studies not specifically designed to test non-inferiority of PAE compared to established approaches.

In a 2021 systematic review and meta-analysis, Xiang et al. investigated the efficacy and safety of PAE versus TURP in individuals with BPH. Eleven randomized controlled trials (RCTs) met the selection criteria, and ten independent patient series were included in the final analysis. Pooled estimates were inconclusive for the difference between TURP and PAE for patient-reported outcomes including International Prostate Symptom Score [2.32 (-0.44 to 5.09)] and quality of life [0.18 (-0.41 to 0.77)] at 12 months. PAE was less effective regarding improvements in most functional outcomes such as maximum flow rate, prostate volume, and prostate-specific antigen. PAE may however be associated with relatively fewer complications, lower cost, and shorter hospitalization. After the PAE procedure, the overall weighted mean differences for all outcomes except sexual health scores were significantly improved from baseline during follow-up to 24 months. The authors concluded that PAE is non-inferior to TURP with regard to improving patient-reported outcomes, though most functional parameters undergo more improvement after TURP than after PAE. They also concluded that PAE can significantly continue to relieve symptoms for 24 months without causing serious complications. The findings are limited by the overall sample size that may have been too small to demonstrate non-inferiority. For example, the upper limit of the pooled estimate for the International Prostate Symptom Score was 5 on a scale from 0 to 35. Furthermore, inferiority of PEA, compared to TURP was shown on other outcomes, with the exception of adverse events.

Xu et al. (2021) conducted a small case series to assess the safety and efficacy of PAE for large BPH and severe LUTS in twenty eight patients over the age of eighty who were not suitable candidates for open or endoscopic surgical procedures. PAE was performed using microspheres and functional outcomes including International Prostate Symptom Score (IPSS), quality of life (QoL), maximum urine flow rate (Qmax), post-void residual urine volume, prostate volume, and total prostate-specific antigen level were evaluated at 1, 3, 6, and 12 months postoperatively. Safety was evaluated using perioperative data and included operative time, fluoroscopy time, changes in hemoglobin within 24 hours postoperatively, hospitalization days, postoperative duration, as well as complications. Bilateral PAE was performed in twenty five patients, and two received unilateral PAE. The results showed technical success with PAE in twenty seven of the participants. All of the functional outcome's results were significantly improved at twelve months postoperatively compared to baseline. The overall complication rate was 46.4%, and included post-embolization syndrome, hematuria, urinary tract infection, and acute urinary retention. The authors concluded that PAE may be an effective treatment option for patients with BPH that are not suitable candidates for open or endoscopic procedures following failed treatments. This study is limited by a lack of comparison group, a small number of participants and a short follow up period. Furthermore, radiation doses and fluoroscopy time were not examined.

In 2021, Abt et al. reported the two-year safety and efficacy outcomes of the open label, randomized non-inferiority trial they conducted in 2018 for which 12-week outcomes were reported previously. In the 2018 trial (included in the Xiang systematic review), 103 participants aged 40 or greater with refractory LUTS secondary to benign prostatic obstruction (BPO) were treated with either PAE using 250-400 µm microspheres under local anesthesia, or monopolar transurethral resection of the prostate (TURP) under spinal or general anesthesia. International Prostate Symptoms Score (IPSS) and other patient reported outcomes, functional measures, prostate volume, and adverse events were evaluated. Changes from baseline to two years were tested for differences between the two interventions with standard two-sided tests. For the participants that received PAE, the results showed the mean reduction in IPSS was 9.21 points, and 12.09 points after TURP [difference of 2.88 (95% confidence interval 0.04-5.72); p = 0.047]. TURP showed superiority for most other patient reported outcomes as well (except erectile dysfunction), including maximum urinary flow rate, reduction of postvoid residual urine, and reduction of prostate volume. Adverse events were less frequent after PAE than after TURP, but the severity was similar. 21% of participants who initially received PAE required TURP within two 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 re-treatment rate found two years after PAE compared with TURP. These disadvantages should be considered for patient selection and counseling.

Pisco et al. (2020) conducted a randomized clinical trial to assess the safety and efficacy of PAE versus a sham procedure for BPH related LUTS in individuals with severe LUTS refractory to medical management with alpha blockers.

Following catheterization of a prostatic artery, eighty participants ≥ 45 years of age were randomized 1:1 to receive PAE or the sham procedure of no embolization. Primary outcomes were assessed at six months and included the change in IPSS and QoL from baseline. Secondary outcomes included BPH Impact Index, IIEF-5, PV, Qmax, PVER and PSA. Study population ages ranged from 48-76 and both arms had similar baseline characteristics. The results showed in the PAE group, a change in IPSS score from 25.5 to 8.75 and the sham group from 27.5 to 21.9. For the QoL measurement, the sham group showed 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 (91.9%) participants were still taking medication at the end of the main study, compared with only two (5.13%) in the PAE group. Regarding adverse events, sixteen occurred in the PAE group, and seventeen in the sham group. These included pain, bruising, hematospermia, hematuria and three patients experienced inguinal hematoma. Two participants with dysuria and burning urethral pain, and one urinary tract infection were medically managed. One participant experienced expelled prostate fragments that caused urinary hematuria and was treated by TURP. All others subsided spontaneously. The authors concluded that PAE is a safe and effective treatment for BPH related LUTS 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, inclusion of only severe LUTS with larger prostate sizes making extrapolation for less severe LUTS or smaller prostates not possible. Future research with longer follow up and comparisons to other treatments are needed to validate these findings.

In 2019, Zumstein et al. performed a systematic review and meta-analysis of clinical trials comparing the efficacy and safety of prostate artery embolization (PAE) to established surgical therapies. Functional parameters assessed included maximum urinary flow, post void residual, and reduction of prostate volume. There were five comparative studies consisting of 708 patients, some of which had an unclear risk of bias in patient selection, blinding, and incomplete outcome data. Reporting of complications varied widely and was poor in some. The results showed that compared to standard surgical therapies PAE showed less improvement in the International Prostate Symptom Score and was less efficient in a in all functional parameters assessed. Conversely, patient 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 patient reported and functional outcomes assessed compared to established surgical therapies were identified. This suggests PAE is not as effective as established surgical therapies. The authors recommend large scale randomized controlled trials that include longer follow up, as well as defining ideal indications are mandatory before PAE can be considered a standard treatment option.

In a 2019 retrospective study, Tian et al. assessed the safety and efficacy of PAE for treating gross 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, and IPSS and QoL were recorded. The results showed gross hematuria was resolved as follows: day 1 in 1 patient, day 2 in 10 patients, day 3 in 4 patients' day 4 in 3 patients, and day 5 in 2 patients. At 3 month follow up, 3 patients reported recurrent hematuria and underwent TURP, and at 12 months hematuria had recurred in 1 of the remaining 17 patients. Regarding IPSS and Qol, scores were available for 18 out of the 20 participants and showed a mean decrease in IPSS from 21.1 to 9.8, and QoL from 5.1 to 1.3. At 12 months the scores for 15 patients showed IPPS 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 7 patients, and resolved with treatment. The authors concluded that PAE is safe and effective and is a reasonable choice of treatment for patients 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 participants. 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 at three, twelve, and eighteen months using QoL, IPSS IIEF and clinical review. The results showed that bilateral PAE was technically successful in all 12 individuals. At three month follow up, all hematuria was resolved. Improvements were seen in IPSS, IIEF and QoL scores and there were no adverse events reported (post embolization syndrome, non-target embolization, or access site complications). The only case of recurrent hematuria was in a patient 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 lack of comparison group, the small number of participants and reliance on patients 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 thirty 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. Patients with neurogenic disorders or who has less than 3 months follow up were excluded. Patients with a baseline PSA > 4 underwent prostate biopsy to rule out malignancy. Twenty-four had indwelling catheters

and 6 were using intermittent catheterization. Patients were assessed at three, six, and twelve months. The results showed embolization was clinically successful in twenty six patients, The mean time to catheter discontinuation was eighteen days and these patients were catheter free at three months follow up. Additional follow up of twenty four patients at six months and seventeen patients at twelve months showed none required reintroduction of catheterization, and IPSS and QoL improved significantly from baseline. At three month follow up, twenty three patients had discontinued all use of medications. Grade I complications occurred in twelve patients and predominantly consisted of hematuria, and all were resolved with the use of urinary analgesics or antimuscarinic medications. The author concluded that PAE is a safe and effective treatment for patients who are not surgical candidates, with clinical benefit lasting at least twelve months. This study is limited by a small number of participants and lack of a control group and further research is needed to validate these findings before firm recommendations as a treatment option can be made.

Abt et al. (2018, included in the systematic review by Xiang et al., 2021, and Sajan et.al., 2022) conducted a randomized, open label, non-inferiority trial in the urology and radiology departments of a Swiss tertiary care center. One hundred and three participants aged ≥ 40 years with refractory lower urinary tract symptoms secondary to benign prostatic hyperplasia were randomized to receive prostatic artery embolization (PAE) with 250-400 μm microspheres under local anesthesia, or monopolar transurethral resection of the prostate (TURP) under spinal or general anesthesia. Forty eight and fifty one patients reached the primary endpoint twelve weeks after PAE and TURP, respectively. Primary outcome was change in international prostate symptoms score (IPSS) from baseline to twelve weeks after surgery (a difference of less than three points between treatments was defined as non-inferiority for PAE and tested with a one-sided t test). Secondary outcomes included further questionnaires functional measures, magnetic resonance imaging findings, and adverse events. Changes from baseline to twelve weeks were compared between treatments with two sided tests for superiority. The authors failed to prove non-inferiority for the primary outcome [1.54 points in favor of TURP (95% confidence interval −1.45 to 4.52)], but fewer adverse events occurred after PAE than after TURP (36 v 70 events; p = 0.003).

Rampoldi et al. (2017) conduced a prospective case series to assess the technical feasibility, safety, and efficacy of PAE for the treatment of bladder outlet obstruction (BOO) LUTS due to BPH managed with indwelling bladder catheterization (IBC) in poor surgical candidates. Forty individuals that 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 individuals had oncologic comorbidities including multiple myeloma, leukemia, 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. Twenty individuals were not eligible for uroflowmetry due to continued IBC or poor clinical status. Bilateral embolization was achieved in one procedure for thirty individuals and two required a second procedure. Unilateral embolization was performed in eight individuals and the procedure was aborted in two due to hypogastric prostate artery stenosis. The mean follow-up time was thirteen months. At six month follow up, the results showed prostate size and IPSS score reduction. Clavien II complications were reported in nine individuals and included UTI, episodes of acute urinary retention requiring temporary IDC placement. Nine participants experienced post embolization syndrome in the forty right hours following the procedure. The results showed that IBC removal was achieved in thirty three patients at follow up. It was concluded that PAE is a safe and efficacious procedure in patients who are poor surgical candidates with no other treatment options.

In a 2016 prospective study, Gabr et al. evaluated the efficacy and safety of PAE in patients with BPH refractory to medication management or had an IDC due to urine retention at a high risk for surgery and/or anesthesia. Twenty-two patients with a mean age of 72 and mean prostate volume of 77 were included. All were not eligible for standard BPH surgical treatment due to high surgical risk due to comorbidities. All patients had an American Society of Anesthesiologists (ASA) score of 3. Pre-operative and one, three and nine month post-treatment assessments included IPSS, IIEF-5, a physical examination, urinalysis, CBC serum creatinine, coagulation profile, PSA, uroflowmetry, and abdominal and transrectal ultrasound. Exclusion criteria included patients with IPSS < 8, prostate size < 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, and other urethral/bladder abnormalities, advanced atherosclerosis or tortuosity of the aortic bifurcation, prostate or internal iliac arteries, as well as those with medical condition that contraindicate iodine contrast media. The results showed technical success in all twenty two patients, and no procedural complications were experienced. In the first month of follow-up, fifteen patients developed a urinary tract infection which responded to antibiotics. All patients were able to successfully urinate after catheter removal, and baseline clinical parameters were improved from first follow up through nine months. There was also 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 LUTS in patients that are high risk for surgery and/or anesthesia. This study is limited by a lack of comparison group, lack of randomization, a short follow up period and a 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. Identified literature is limited to expert opinions and observational studies. Furthermore, findings for oncological outcomes are conflicting and limited by short-term follow-up.

Iacovelli et al. (2024) conducted a prospective single-center interventional pilot study to evaluate the oncological and functional outcomes of TPLA for localized PCa in 24 participants with stage < T2 disease, PSA < 20 ng/mL, International Society of Urological Pathology (ISUP) grade ≤ 2, MRI-fusion biopsy confirmed disease. Individuals with previous pelvic radiation, a history of other genitourinary malignancies, multifocal disease or tumor diameter ≥ 2 cm or had no MRI data were excluded. Post-operative follow up visits were conducted at 3, 6, and 12 months, and mpMRI was performed at months 3 and 12. All participants underwent re-biopsy at 12 months. The results showed improvement in IPSS, IPSS-QoL and ICIQ-SF scores at 3 months, and erectile and ejaculatory functions showed no significant variation during follow up. Oncological outcomes showed 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, 7 were confirmed to have recurrent PCa with 3 showing recurrence of the target lesion. No AEs or readmission was reported. The authors concluded that TPLA is a safe and effective treatment for individuals with low and intermediate risk prostate cancer despite a lack of proper radiological methods to show the effects of TPLA on prostatic tissue and to detect eventual PCa relapses. This pilot study is limited by a 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 (FT) to standard current treatment options for clinically localized prostate cancer (PCa). Four primary studies [one randomized controlled trial (RCT) and three retrospective studies] including 3,961 patients, (and ten eligible SRs were identified) reporting on different types of FT. The results showed the following: The RCT compared photodynamic therapy (PDT) with active surveillance and a retrospective matched-pair study comparing focal high-intensity focused ultrasound (HIFU) with robotic radical prostatectomy (RP). Two retrospective SEER-based, propensity- matched cohort studies compared focal laser ablation (FLA) against radical prostatectomy (RP) and external beam radiotherapy (EBRT), reporting significantly worse overall survival with FLA on adjusted analysis. The authors concluded that overall, the evidence in support of FT as an alternative to either AS or radical interventions for localized PCa was limited. Data regarding the oncological effectiveness were mixed and inconsistent. For FLA specifically, limited quality data suggest harm, as compared to alternative, established therapies. Overall, for FT, 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, interventions (e.g., intermingling of whole-gland and FT 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 SRs confirmed these findings, and none showed high-certainty evidence. The authors concluded that the routine use of FT 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.

In a 2019 Delphi consensus project following a systematic review of the literature, van Luijtelaar et al. presented the evidence-based consensus of 37 international experts in the field of focal therapy for PCa. Consensus was agreed upon in 39/43 topics. Clinically significant PCa (csPCa) was defined as any volume Grade Group 2 [Gleason score (GS) 3 + 4]. Focal therapy was specified as treatment of all csPCa and can be considered primary treatment as an alternative to radical treatment in carefully selected patients. In patients with intermediate-risk PCa (GS 3 + 4) as well as patients with MRI-visible and biopsy-confirmed local recurrence, the experts felt that FLA is optimal for targeted ablation of a specific magnetic resonance imaging (MRI)-visible focus. However, FLA should not be applied to candidates for active surveillance and close follow-up is required. Suitability for FLA is based on tumor volume, location to vital structures, GS, MRI-visibility, and biopsy confirmation. The expert consensus concluded that FLA is a promising technique for treatment of clinically localized PCa and should ideally be performed within approved clinical trials. They noted that there are only a few studies have reported on FLA and further validation with longer follow-up is mandatory before widespread clinical implementation is justified.

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. Thirty-seven articles reporting on 3,230 individuals undergoing focal therapy were selected. Thirteen reported on high-intensity focused ultrasound, eleven on cryotherapy, three on photodynamic therapy, four on laser interstitial thermotherapy, two on brachytherapy, three on irreversible electroporation, and one on radiofrequency. Laser interstitial thermotherapy has been evaluated in up to Stage 2a studies. Median follow-up varied between four months and sixty one 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 83.3-100% and 81.5-100%, 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 quality of life and genitourinary function, the oncological effectiveness has not been defined against the current standard of care. The author identified limitations of this SR include the length of follow-up, the absence of a comparator arm, and study heterogeneity.

Transperineal Laser Ablation (TPLA)

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

Bertolo et al. (2023) conducted a single-center, prospective, randomized open-label study to evaluate TPLA for the preservation of antegrade ejaculation as compared to TURP with BPO. Participants must have normal ejaculatory function and the presence of antegrade ejaculation prior to surgery, IPSS score ≥ 10, Qmax of < 15 mL/s; prostate volume at preoperative ultrasonography < 100 mL and normal preoperative urine analysis. 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's 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 impacting voiding. Fifty-one participants were randomized 1:1 to received TPLA (26) or TURP (25) and were assessed at one 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 with regard to the IIEF-5 score, and the ejaculatory function status was unchanged in the treatment group, however the control group showed an 11 point decrease. The absence of antegrade ejaculation was reported by only one participant in the TPLA group compared to eighteen in the TURP group. Uroflowmetry results showed that participants that received TURP had a mean improvement of 23.9 mL/s compared to 6.0 mL/s in the TPLA group. Both treatments showed statistically significant improvements in IPSS and QoL scores, with TURP having a higher impact on IPSS. A significantly higher number of patients 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 show 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 LUTS. Six articles, (two retrospective and four prospective) comprised of 287 individuals were included. The primary outcomes were improvements in Qmax, PVR and LUTS relief, secondary outcomes were preservation of sexual and ejaculatory function assessed by IEEF-5 and MSHQ-EjD questionnaires and rates of post operative complications. Outcomes were assessed at one, three, six, and twelve months post operatively in all of the studies. The results showed statistically significant improvement in mean Qmax, PVR, 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 reported among the included patients included one intraoperative urethral burn, two prostatic abscesses, four cases of hematuria, one case of orchitis, three experienced acute urinary retention and six patients experienced transient dysuria. The authors concluded that TPLA shows promising results in pilot studies, and more research is needed to compare TPLA to standard treatments. This systematic review is limited by a lack of comparison groups, small number of participants 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 of TURP vs. TPLA for the treatment of BPH. Fifty participants aged 50 and over who were candidates for TURP, with IPSS > 12, Qmax ≤ 15 were included and randomized 1:1 to receive TURP or TPLA. IPSS, IEFF-5, MSHQ-EjD, and QoL assessments were completed by participants at baseline and at 12 months. Qmax, PV, and PVR data was recorded. The results showed a statistically significant improvement in IPSS, Qmax, and PVR compared to baseline values in both groups at one 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 on the TURP group. PVR was similar in both groups. The authors concluded that BPH symptom improvement using TPLA is comparable to TURP and results in less ejaculatory dysfunction and can be a treatment alternative in patients who wish to preserve EF, as well as those who are 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.

An ECRI clinical evidence assessment focused on TPLA's safety and effectiveness and compared it to TURP and other minimally invasive BPH treatments (2022). The report included four prospective and two retrospective before and after studies. The four prospective studies compared patients with BPH before and after undergoing TPLA. The results reported on hospital length of stay (LOS), catheterization duration, medication usage, symptoms, and QOL [measured on the International Prostate Symptom Score (IPSS), sexual health, and adverse effects (AEs); the data was measured at one, three, six, and/or twelve-month follow-up]. The single-center retrospective study included 20 participants with BPH and also reported symptoms before and after undergoing TPLA. Data measured included patient reported symptoms, QOL and AEs at six-month follow-up. A multicenter before and after study of 160 participants measured hospital LOS, catheterization duration, QOL and AEs at 6- and 12-month follow-up. The results appear to show TPLA as promising, safe, and effective. However, limitations included small sample sizes, no comparative studies, and a high risk of bias due to two or more of the following: retrospective design, single-center focus, and lack of control groups and randomization. Further large, multicenter RCTs are needed to validate the studies' findings and to compare TPLA with other treatments. The overall conclusion of the report is that the evidence is inconclusive.

Temporary Urethral Stents

The quality of the evidence is insufficient to support the efficacy and safety of this technology. One identified RCT provides mixed findings and a large loss to follow up, while one comparative observational study is limited by indirect comparisons and does not demonstrate non-inferiority, compared to PUL, on efficacy and serious treatment-related adverse event outcomes. Additional publications are limited by single-arm designs.

In a 2023 matching-adjusted indirect comparison (MAIC) study, Kernen et al. evaluated the safety and efficacy of the iTind versus the PUL (UroLift) for the treatment of LUTS due to BPH in the first twelve months following treatment. Seven clinical trials were included. Deidentified individual patient data was received from the manufacturer of the iTind for the group that received the device, and aggregated data from PUL from two randomized controlled trials and two single arm trials was used for the group receiving the UroLift device. Patient demographics included iTind or PUL treatment only, at least age 45 with baseline prostate volume of < 80mL, IPSS ≥ 10 and no obstructive median lobe. Safety was evaluated by the percentage of participants that experienced treatment related adverse effects. Efficacy was evaluated via changes from baseline to twelve months via IPSS, QoL, peak urinary flow (Qmax), post void residual volume (PVR) and sexual health. The results showed that there were common AEs experienced in both treatment groups and these included dysuria, hematuria, pain, urgency urinary incontinence and retention and urinary tract infection. In the first three months, these were significantly higher in the match-adjusted iTind group (25% vs. 79.8%). AEs at three through twelve months were also significantly lower in the iTind population than the pooled PUL population (2.6% vs. 24.4%). Serious treatment-related adverse events were not statistically significantly different between groups but were more frequent at three months for iTind than for PUL (2.2% vs. 0.5%, p = 0.2). Regarding efficacy, there were no significant differences from baseline between the two groups. Return to normal activity levels were significantly lower in the iTind group by 4.35 days. No studies reported any instances of sustained erectile dysfunction, or retrograde ejaculation. The authors concluded that individuals achieved equivalent efficacy outcomes with significantly less adverse outcomes. Additional independent research is needed to validate these findings. This MAIC is limited by the indirect comparison between the two treatments as well as the superiority of the comparator on several outcomes.

A Hayes (2022, updated in 2024) emerging technology report identifies limited evidence and minimal support for the use of the iTind system, and provides no clear indication regarding which individuals may be candidates. Positive efficacy and safety results from the studies may not be applicable to patients with larger prostate volumes (> 75 cubic centimeters) or with median lobe etiology as these subgroups were not well represented or were excluded. Additionally, there were no data for more complex patients who have history of prostate cancer or prostate surgery, urethral stricture, and concomitant bladder stones. Four ongoing clinical studies, including one comparing iTind with Rezūm and one comparing iTind with UroLift, should provide clarity around the durability of treatment and comparative effectiveness relative to other minimally invasive BPH treatments.

A 2022 ECRI clinical evidence assessment, updated in 2023 on the iTind System (Olympus America, Inc.) for treating benign prostatic hyperplasia, concluded that while iTind appears to be safe and effective, published studies included too few patients and a high risk of bias, therefore are inconclusive.

Amapore et al. (2021) reported the three 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 eighty one participants with LUTS due to benign prostatic obstruction (BPO). Baseline measurements were as follows: IPSS ≥ 10, peak urinary flow < 12 mL/s and prostate volume < 75 mL. Outcomes assessed included OR-time, pain (VAS) postoperative complications (Clavien-Dindo-Grading System), functional results (Qmax, IPSS, PVR) and quality of life (QoL) and were assessed at one, three, and six months and one, two, and three 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 urinary tract infection. There were eight cases of urinary retention reported. At three year follow up, data were available for fifty of the original eighty one participants and the results showed that the efficacy of iTind remained stable, with significant improvements from baseline in IPSS, QOL, Qmax, and PVR of -58.2%, -55.6%, +114.7%, and -85.4% respectively (the ITT patient population included those patients who were identified as having median lobes which was found to be a predictor for treatment failure between twelve and twenty four months of follow-up). No adverse events were recorded between twelve and thirty six months, and none of the patients who were previously sexually active reported sexual or ejaculatory dysfunction. From baseline to twenty four 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 shows significant and durable improvements at three year follow up. In 2023, Amapore et al. reported the long term (50-79 months) results of this study. Due to the COVID-19 pandemic, patients could not be seen in person for objective tests for follow up and 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 forty eight months. There were low rates of complications and adverse events and included UTI, hematuria, and postoperative pain. All of which occurred within thirty days and were self-resolving. There was no effect in erectile or ejaculatory function. This study is limited by the lack of a control arm comparing iTind to other procedures or sham and small number of participants. Furthermore, due to the COVID-19 pandemic, only 50% of participants were available for more than forty eight months of follow up, and only subjective information was reported.

Chughai et al. (2020, included in ECRI clinical evidence assessment) conducted a RCT that compared a temporarily implanted nitinol device (iTind) to sham in 175 participants with lower urinary tract symptoms due to benign prostatic hyperplasia (BPH). Inclusion criteria for the participants were individuals 50 years of age or older, an International Prostate Symptoms Score (IPSS) of ≥ 10, peak urinary flow rate (PFR) of ≤ 12 mL/sec with a 125 mL voided volume, and prostate volume between 25 and 75 cc. Subjects 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 three months post procedure. In the intention to treat population, the iTind arm improved IPSS by -9.0 ±8.5 (22.1-13.0) while the sham arm improved -6.6 ±9.5 (22.8-15.8) (p = 0.063) at three months. A total of 78.6% of participants in the iTind arm showed a reduction of ≥ 3 points in IPSS, vs. 60% in the control arm at three months (p = .029). Adverse events occurred in 38.1% of individuals 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, quality of life, or sexual function. The authors found iTIND to be durable for twelve months with only 4.7% of participants having undergone another surgical intervention for BPH. 78.6% of the participants receiving the iTIND had improvement of their IPSS score. Limitations included mixed results, loss to follow-up of almost 30% of participants, and specific inclusion criteria that could or could not be applied to all males with BPH.

Porpiglia et al. (2018) reported 3-year outcomes from a prospective case series study involving the temporary implantable nitinol device (iTIND) implantation for the treatment of BPH. Thirty-two patients with LUTS were enrolled. Follow-up assessments were made at three and six weeks, and three, six, twelve, twenty four, and thirty six months after the implantation. The change from baseline in IPSS, QOL score and Qmax was significant at every follow-up time point. After thirty six months of follow-up, a 41% rise in Qmax was achieved (mean 10.1 mL/s), the median (IQR) IPSS was 12 (6-24) and the IPSS QoL was 2 (1-4). Four early complications (12.5%) were recorded, including one case of urinary retention (3.1%), one case of transient incontinence due to device displacement (3.1%), and two cases of infection (6.2%). No further complications were recorded during the 36-month follow-up. In the authors' opinion, the extended follow-up period supports the temporary stent to be safe, effective, and well-tolerated. Lack of comparison group or randomization and small patient population are limitations to this study.

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. Identified literature appears to be limited to a small phase I trial.

Johannsen et al. (2007) conducted a prospective phase I clinical trial in ten individuals with locally recurrent prostate cancer following treatment with a curative intent. Inclusion criteria also included a serum prostate-specific antigen (PSA)-value < 20 ng/mL and ECOG performance status of 0-1. Participants were excluded if they had advanced imaging evidence of systemic disease, the 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 or refused salvage radical prostatectomy. Primary endpoints included feasibility, toxicity, and QoL. Following intraprostatic injection of nanoparticles, six thermal therapy sessions of sixty 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 pre-irradiated prostate tissue was difficult to achieve and one received five thermotherapy sessions, not six. Alternating magnetic field strengths of 4-5 kA/m were tolerated throughout the treatment time in all patients. A minor rise in pulse and blood pressure occurred in some patients towards 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 two to four weeks due to acute urinary retention was necessary in four patients (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. Dysuria grade 2 was present in two and grade 1 in three participants. In one participant, a febrile urinary tract infection 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 thermos-ablative temperatures may cause heating outside the target volume in a proportion of patients as well as local discomfort during thermal treatments, and intratumor distribution of the nanoparticles is inconsistent and challenging, and 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 lack of comparison group beyond three months and lack of comparison to established therapies.

In a 2024 ECRI clinical evidence assessment, it was concluded that evidence from a multicenter, double-masked, sham-controlled randomized controlled trial (RCT) indicates 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 suggest the efficacy of Optilume is maintained through four-year follow-up. No studies comparing Optilume with other BPH treatments were found.

In the 2023 PINNACLE study, a double-blind 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 LUTS due to BPH. One hundred forty-eight individuals between 50 and 80 years old with symptomatic BPH, IPSS ≥ 13, Qmax between 5-12 mL/s, a prostate volume between 20 and 80 g, and a prostatic urethral length of 32-55 were randomized 2:1 to receive treatment with Optilume BPH or a sham procedure in which the balloon was not inflated. One hundred received the Optilume BPH, and 48 received a sham procedure. After 3 month follow up, participants in the sham arm were allowed to cross over to the treatment arm. Exclusion criteria included prior prostate procedures, PSA > 10 without a negative biopsy, diagnosis or suspicion of bladder or prostate cancer active UTI, PVR > 300 mL, and any other condition that could impact urinary function. Blinding was maintained in participants and assessors through one year post procedure. Follow up was conducted at fourteen and 30 days, and six and twelve 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 one year, compared to an average of 8.0 in the sham arm at three months. The change in Qmax scores were also significantly improved in the treatment arm. PVR also improved from 83 mL at baseline to 58 mL at one year. Sexual function was not significantly impacted and both arms showed mild improvement. Four participants in the treatment arm reported an adverse ejaculatory dysfunction compared to one in the sham arm. No erectile dysfunction was reported. Four cases of post procedural hematuria that required cystoscopy management or extended observation were reported and one urethral false passage that required extended catheterization. The authors concluded that the Optilume System produces clinically meaningful results for the treatment of LUTS secondary to BPH immediately and is sustained through one 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 two year outcomes of this study. Seventy seven of the treatment arm were available and the results showed that at two years, 67% of the participants were responsive as defined by ≥ 30% improvement without any medical or surgical retreatment. IPSS scores improved 50.8%, Qmax improved 116% from 8.9 to 19.0 and PRV showed a slight reduction. BPH-II improved from 7.0 to 2.3 at one year and this remained consistent to two years. The most common AEs were hematuria and UTI and no device and/or serious AEs were reported after one year. There was no impact on sexual function. Improvement in uroflowmetry measures was consistent across all prostate volumes. Surgical re-intervention 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 alpha blockers, PDE5 inhibitors, 5-ARIs, and supplements. The authors concluded that at two year follow up in the PINNACLE study, participants treated with the Optilume BPH Catheter showed sustained improvement in symptoms and functional outcomes, confirming effectiveness and longer term outcomes with a safety profile comparable to other minimally invasive treatments.

In 2021, Kaplan et al. reported the one 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 LUTS secondary to BPH. The EVEREST study was conducted in six centers in the Dominican Republic and Panama, and included individuals over the age 50 with an IPSS score ≥ 13, peak Qmax 5-15 mL/sec with minimum voided volume of ≥ 125 mL, PVR ≤ 250 mL, prostate volume 20-80g, and prostatic urethra length 35-55 mm. Participants were followed at two-five days (catheter removal), two weeks, thirty days, three and six months, and one year. The primary endpoint was based on a modified intent to treat population and was ≥ 40% improvement in IPSS scores at 3 months, secondary measures includes IPSS, Qmax, pain, sexual function, and AEs. Seventy five of the original 80 participants were available for one year follow up and the results showed 81.3% of participants reached the primary endpoint at 3 months. Secondary endpoints all showed sustained improvement through one-year follow up with more than 70% having at least 50% improvement in IPSS from thirty days onward with approximately half achieving 75% improvement by one year. Qmax scores also increased from baseline thorough one year, and IPSS QoL improved by 70.7%. There was no deterioration in sexual function and ejaculatory function was preserved. One hundred and thirteen AEs were reported through the one year follow up and the majority occurred within three months of treatment, and the most frequent were post-procedural hematuria (15.0%), post-operative urinary retention (13.8%), urinary incontinence (13.8%), urinary tract infection (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 four year outcomes of this study. These results included the primary endpoints of functional assessments and symptomology. Of the original eighty participants, fifty nine were available for this four year follow up. At four 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 MSH QEjD, was preserved at four years, with no statistically significant change for any measure. A total of one hundred and thirty six AEs were reported in fifty six participants through four years with the majority occurring within three months of the procedure, and no treatment related AEs from months twenty four through forty eight. This longer term follow up shows that symptom improvement originally obtained from treatment with the Optilume catheter was sustained through four years. The findings of this study are limited by the single-arm design.

Transurethral Thermal Ultrasound Ablation (TULSA)

Transurethral thermal ultrasound ablation 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 participants.

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 magnetic resonance imaging-guided transurethral ultrasound ablation in 115 individuals with favorable to intermediate risk prostate cancer across 13 centers that were treated with whole gland ablation sparing the urethra and a 3 mm margin at the apical sphincter. Inclusion criteria was individuals aged 45-80, Gleason Grade (GG) 1 to 2 cancer with clinical stage T2b or less, PSA 15 ng/mL or less, minimum 10-core biopsy, no previous treatment, and the ability to undergo MRI. Participants were excluded if they had any or the following: 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 or calcifications greater than 1 cm. The safety results showed that a total of 12 severe (Grade 3) adverse events occurred in 9 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 ED and 3 had moderate urinary incontinence. Two participants had recurrent urinary tract infections at 12 months. Urethral stricture occurred in 3, urinary retention in 10, and moderate abdominal or rectal discomfort was experienced. Efficacy results showed at 12 month follow up, a reduction in PSA greater than 75% was achieved in 110 participants (two of 115 patients 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. Patient reported measures of erectile function and overall sexual function and satisfaction showed there was an initial decrease in these domains followed by gradual recovery, and ultimately a third experienced moderate decreased sexual function at 12 months. Ninety-two 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 endpoint was met, as defined by regulators to assess the efficacy of TULSA as a prostate tissue ablation device. The authors concluded that TULSA is effective ablative treatment for prostate cancer and has a favorable side effect profile with minimal impact on quality of life. 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 PCa 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 PET-CT. In the absence of a visible lesion, systematic biopsies were taken. Staging ranged from T1-T3 and 10 had previous EBRT and one HDR. Median prostate volume was 21 cm^3, median PSA was 7.6 ng/mL. All participants underwent cystoscopy before sTULSA to assure sufficient urethra patency for the device, and underwent either whole (8) or partial gland (3) ablation, depending on disease characteristics. Follow up occurred at 3 month intervals. The results showed that sTULSA was feasible in all participants. There were one Grade 3 and 3 Grade 2 urinary adverse events that included urinary infection and retention in four participants. Ten patients were free of catheterization at 1 yr, with one patient 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 mo. were 27% and 24%, respectively, and the decrease in voided volume from baseline to 12 mo. was 54%. The only participant that had received a prior salvage treatment had an increase in postvoid residual volume (PVR) post treatment. Patient reported functional outcomes showed overall improvement at 12 month follow up and three participants required mirabegron for urinary urgency. No lesions were observed at 3 mo. on mpMRI and at 12 mo., 10 individuals showed no PCa in the targeted ablation zone, and had low and stable PSA. Two of the 11 individuals had an out-of-field recurrence. The authors concluded that sTULSA appears to be safe and feasible for salvage treatment of radio recurrent PCa. 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. Thirty treatment naïve individuals ≥ 65 with confirmed stage T1c-T2a, N0, M0 PCa, PSA ≤ 10 ng/mL, and Gleason score (GS) 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 endpoints explored were PSA, IPSS, erectile function domain of the IIEF-15, and bowel habits domain of University of California, Los Angeles Prostate Cancer Index-Short Form (UCLA-PCI-SF), The results showed that there was no of ablative heating thermometry of the external urinary sphincter or rectal wall. Immediate post-treatment 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 G4 or higher adverse events and only one attributable G3 event (epididymitis). The majority were G1 and G2 events that occurred and resolved within the first 3 months and included approximately 10 urinary tract infections. Cystoscopy was performed at the 12-mo visit specifically to assess urethral strictures and showed an incidental finding of an asymptomatic urethral stricture G1 in one patient requiring no action and a G2 stricture that was resolved with a urethral dilator. Exploratory outcomes showed median IPSS scores increased at one month, with a return to baseline at 3 months with symptom improvement in 17 participants. Median IIEF-15 erectile function decreased initially and returned to baseline by 12 months. Median PSA decreased 87% at one month, was stable at to 12 month follow up. MRI and TRUS prostate biopsy at 12 mo. showed diminished prostate volumes, averaging 51% fibrosis. Biopsies were positive for clinically significant disease in 9 of 29 participants. Positive biopsies for any disease were obtained in 16 of 29 patients 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 the ability to thermally ablate target tissues to within 1.3 mm and well-tolerated side effects with minor or no impact on urinary, erectile, and bowel function at 12 months. Oncological outcomes were not primary or secondary outcomes assessed so conclusions cannot be made. Furthermore, the safety requirement of the trial required targeting the inner 90% of the prostate without an attempt to target specific foci which 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 3 year follow up. The authors stated that this trial data provides evidence for further study of MRI-TULSA in larger patient populations. In 2021, Nair et al. reported on the three year outcomes of this clinical trial in 22 of the 30 participants. outcome assessment which included AEs, functional QoL and PSA, as well as biopsy, feasibility, and safety. At 3 year follow up, 22 participants had remained on protocol mandated follow up. One withdrew after refusing 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 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. Seven participants that showed positive for insignificant disease at the 12-month biopsy, four underwent salvage radical prostatectomy (RP). Of the nine patients who had clinically significant disease at 12-months, five had salvage treatment. BCR was seen in eight patients, with an estimated 3-year BCR-free survival of 74%. Safety results showed no AEs ≥ 4 and no rectal injuries or fistulae and no new significant AEs developing between 12 and 36 months. Most of the AEs at 12 months resolved before the 3-year visit, and there were 12 AEs ongoing in 10 patients. There were no significant differences in erectile function (EF), bowel function, urinary incontinence or 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 PCa. This three 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.

Clinical Practice Guidelines

American Urological Association (AUA)

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

- PUL should be considered as a treatment for patients with LUTS attributed to BPH provided prostate volume 30-80 g and 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 waterjet treatment may be offered to patients provided prostate volume > 30/ < 80 g. (Conditional Recommendation; Evidence Level: Grade C)
- Water vapor thermal therapy:
  - Should be considered as a treatment option for patients with LUTS/BPH with a prostate volume of 30-80 g. 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)
- Prostate artery embolization may be offered for the treatment of LUTS/BPH and performed by clinicians trained in this procedure. (Conditional Recommendation; Evidence level: Grade C)
- Temporary implanted prostatic devices (TIPD) may be offered as a treatment option for patients with LUTS/BPH provided prostate volume is between 25 and 75 g and lack of 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 to 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 estimated life expectancy greater than 10 years, clinicians should offer a choice between radical prostatectomy or radiation therapy plus androgen deprivation therapy (ADT). (Strong Recommendation; Evidence Level: Grade A)

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

In a joint practice guideline on the treatment of non-metastatic muscle-Invasive bladder cancer, the above organizations state that it is a clinical practice (defined as a statement about a component of clinical care that is widely agreed upon by urologists or other clinicians for which there may or may not be evidence in the medical literature) that when performing a standard radical cystectomy, clinicians should remove the bladder, prostate, and seminal vesicles in males.

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 ASCO) state that in patients with biopsy-documented prostate cancer recurrence after primary RT who are candidates for salvage local therapy, clinicians should offer RP, cryoablation, high-intensity focused ultrasound (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." Presently, the panel recommends cryosurgery and HIFU 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 whose cancer is clinically localized to the prostate that can be completely surgically excised, and 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 remains significantly higher than when radical prostatectomy is used as initial therapy.

In the clinical practice guideline for bladder cancer, the NCCN states that radical surgical treatment of bladder cancer involves a cystoprostatectomy which includes removal of the prostate, seminal vesicles, proximal vas deferens, and proximal urethra.

NCCN guidelines do not include recommendations for the use of TULSA.

National Institute for Health and Care Excellence

The NICE interventional procedures recommendation for transurethral water-jet ablation for lower urinary tract symptoms caused by benign prostatic hyperplasia states that there is good quality evidence that the procedure improves lower urinary tract symptoms caused by BPH and is safe consider it as a treatment option.

A NICE medical technology guideline for the use of Rezum for treating lower urinary tract symptoms secondary to benign prostatic hyperplasia states that the evidence supports adopting Rezum for treating lower urinary tract symptoms (LUTS) caused by benign prostatic hyperplasia (BPH). It should be considered as a treatment option for men with moderate to severe LUTS [International Prostate Symptoms Score (IPSS) typically 13 or over], and a moderately enlarged prostate (typically between 30 cm and 80 cm).

The NICE guidelines for prostate artery embolization for lower urinary tract symptoms caused by BPH states 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 prostatic artery embolization.

Society of Interventional Radiology (SIR)

In a 2019 (McWilliams et al.) multi-society, evidence-based position statement regarding PAE for the treatment of lower urinary tract symptoms 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 LUTS (strong recommendation)
- In patients with BPH and moderate to severe LUTS 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 LUTS 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 LUTS 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)

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 lower urinary tract symptoms, including benign prostatic obstruction (BPO), state that the following interventions may be offered with a strong strength of recommendation:

- Bipolar- or monopolar-transurethral resection of the prostate to surgically treat moderate-to-severe LUTS in men with prostate size of 30-80 mL
- Transurethral incision of the prostate to surgically treat moderate-to-severe LUTS in men with prostate size < 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 LUTS in men with prostate size > 80 mL
- Prostatic urethral lift (UroLift®) to men with LUTS interested in preserving ejaculatory function, with prostates < 70 mL and no middle lobe
- Laser enucleation of the prostate using Ho:YAG laser (HoLEP) to men with moderate to-severe LUTS 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 to men with moderate-to-severe LUTS as an alternative to TURP
- Enucleation of the prostate using the Tm:YAG laser (ThuLEP, ThuVEP) to men with:
  - Moderate-to-severe LUTS 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 to men with moderate-to-severe LUTS as a comparable alternative to bipolar transurethral (plasmakinetic) enucleation or bipolar TURP
- Prostatic artery embolization (PAE) for men with moderate-to-severe LUTS who wish to consider minimally invasive treatment options and accept less optimal outcomes compared with TURP, and only be performed in units with highly trained teams
- Aquablation to patients with moderate-to-severe LUTS and a prostate volume of 30-80 mL as an alternative to transurethral resection of the prostate

The EAU states that minimally invasive simple prostatectomy is feasible in men with prostate sizes > 80 mL that 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.

Prostate surgeries are procedures and, therefore, not regulated by the FDA. However, devices and instruments used during the surgery may require FDA approval. Refer to the following website for additional information: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed November 6, 2024)

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 BPH, including lateral and median lobe hyperplasia in men 45 or older. For additional information refer to the following website: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K193269. (Accessed November 6, 2024)

On August 2, 2019, The U.S. Food and Drug Administration (FDA) cleared the Rezūm™ Water Vapor Therapy system (Boston Scientific Corp.) under 510(k) premarket notification for treatment of symptoms of benign prostatic hyperplasia (BPH), and treatment of the prostate with hyperplasia of the central zone and/or a median lobe. It is not approved for 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 November 6, 2024)

The U.S. Food and Drug Administration (FDA) has cleared powered laser devices under 510(k) Premarket Notification. For device specific information, search product codes LLZ, FRN and GEX here: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm. (Accessed October 20, 2023)

The U.S. Food and Drug Administration (FDA) approved the Spanner® Temporary Prostatic Stent (SRS Medical, North Billerica, MA) under its premarket approval (PMA) process on December 14, 2006. 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. Refer to the following website for additional information: https://www.accessdata.fda.gov/cdrh_docs/pdf21/K210138.pdf. (Accessed November 6, 2024)

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 males with lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia. Refer to the following for further information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K202961. (Accessed November 6, 2024)

For information on microsphere products for the treatment of BPH refer to the following website and search by product code NOY: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed October 29, 2024)

The ECHOLASER X4 system received 510(k) Premarket Notification from the FDA in September of 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 June 30, 2023, the Optilume® Urethral Drug Coated Balloon (Urotronic, Minneapolis, MN) received FDA clearance under the premarket approval (PMA) pathway. It is indicated for the treatment of obstructive urinary symptoms associated BPH in men ≥ 50 years of age. For additional information, refer to the following website: https://www.accessdata.fda.gov/cdrh_docs/pdf22/P220029A.pdf. (Accessed November 6, 2024)

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 November 14, 2024)

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Policy History/Revision Information

Date	Summary of Changes

12/01/2025	**Medical Records Documentation Used for Reviews**
	• Removed reference link to the guidelines titled *Medical Records Documentation Used for Reviews*
	• Added language to indicate:
	  ○ The patient's medical record must contain documentation that fully supports the medical necessity for the requested services
	  ○ This documentation includes but is not limited to relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures
	  ○ Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and must be made available upon request
	Supporting Information
	• Archived previous policy version CS334NE.G

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. 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.

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