UnitedHealthcare Community Plan

UnitedHealthcare® Community Plan
Medical Policy

Prostate Surgeries and Interventions(for Kansas Only)

Policy Number: CS334KS.01
Effective Date: June 1, 2025

Instructions for Use

Table of Contents **Page**

Related Policies
None

Application

This Medical Policy only applies to the state of Kansas.

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 and median lobe hyperplasia, in men 45 years of age or older; and
- The following are not present:
  - Prostate volume of > 100 cc
  - A urinary tract infection
  - Urethra conditions that may prevent insertion of delivery system into 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 is unproven and not medically necessary for all other indications.

Transperineal Placement of Biodegradable Material

The transperineal placement of biodegradable material, peri-prostatic (via needle) is proven and medically necessary for use with radiotherapy for treating prostate cancer.

The transperineal placement of biodegradable material, peri-prostatic (via needle) is unproven and not medically necessary for all other indications 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:
- Ineligibility 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.

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

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)

CPT Code	Description
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)
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
55873	Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring)
55874	Transperineal placement of biodegradable material, peri-prostatic, single or multiple injection(s), including image guidance, when performed

CPT® is a registered trademark of the American Medical Association

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 such as transurethral resection of the prostate (TURP) and prostatectomy.

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. It is delivered via an optical fiber inserted through the patient's perineal skin and into the prostate using transrectal ultrasound guidance.
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).

When prostate cancer is treated by radiotherapy, transperineal placement of a biodegradable material is used to protect other pelvic structures during radiotherapy. These devices are used to position the anterior rectal wall away from the prostate during radiotherapy for prostate cancer and are absorbed by the body over time. SpaceOAR™ Hydrogel is a radiopaque polyethylene glycol (PEG) based hydrogel and Barrigel® is a hyaluronic based gel. These are injected transperineally using transrectal ultrasound guidance creating a space between the rectum and the prostate. Both can be visualized on imaging such as CT, MRI, and ultrasound. The BioProtect™ System is a biodegradable balloon spacer that is inserted transperineally between the prostate and the rectum. Using transrectal ultrasound guidance, a blunt insertion device delivers the balloon and it is then filled with sterile saline and sealed in place. Prior to the final seal, the device can be deflated, moved and reinflated as necessary. It is also able to be seen on imaging.

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).

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 15 were for the primary treatment for newly diagnosed cancer. In the 11 primary treatment studies, the results of 10 showed disease specific survival ranged from 90.5 to 100%, 5 reported overall survival rates of 61.3 to 98.7%, 2 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: 27 studies on high-intensity focused ultrasound (HIFU), 9 studies on irreversible electroporation, 11 on cryoablation, 8 on focal laser ablation and focal brachytherapy, 7 on photodynamic therapy (PDT), 2 on radiofrequency ablation, and one on prostatic artery embolization. Of the 11 studies on cryoablation, six were retrospective studies, one of which compared HIFU with cryoablation, and five were prospective studies. No randomized controlled trials (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)

In 2017, Roehrborn et al. published five-year outcomes of the prospective, multicenter, randomized, blinded sham control trial of the PUL in men with bothersome lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH). In this 19-center study, 206 subjects ≥ 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 3 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 5 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 transurethral resection of the prostate (TURP). Inclusion criteria were 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. Patients 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)

In a 2022 comprehensive literature review of 79 studies, Ottaiano et al. evaluated and summarized the complications associated with non-minimally invasive and minimally invasive BPH treatments. When comparing TURP to aquablation, the results showed that following TURP, bleeding ranged from 4-11%, ejaculatory dysfunction 70-90% and retreatment 0-8.3%. Comparatively, following aquablation, bleeding averaged 1.9%, ejaculatory dysfunction 10% and retreatment 2.6%. In the pivotal WATER trial, the overall rates of complication, including urgency, dysuria, frequency and leakage were also lower for aquablation than TURP, as were more serious complications such as bladder neck contractures and strictures. The authors analysis suggests that while TURP remains the gold standard surgical treatment for BPH, there are minimally invasive surgical options that result in similar success rates and lower incidence of treatment related morbidity.

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 a TURP, the gold standard for BPH. 181 men 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 patients were followed for 5 years and staff performing assessments were blinded for 3 years; year 4 and 5 occurred during the COVID-19 pandemic. The primary efficacy endpoint was the change in IPPS from baseline to 6 months and was successfully achieved; at 6 months the aquablation group showed slightly better numbers with an IPSS decrease of 16.9 points from baseline whereas the TURP group had a decrease of 15.1 points. At 5 years, the median IPSS score was 5.5 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 5 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 5 years, uroflow improvement continues to show durability and consistency. Limitations included the loss to follow up rate at year 4 and 5 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 2023, 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.

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.

Gilling et al. (2020 – included in Ottaiano 2022 literature review above) 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-reductase 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 - included in Ottaiano 2022 literature review above) conducted an international prospective, multicenter, single-arm, open-label, international clinical trial of the efficacy of the aquablation procedure for the treatment of LUTS due to BPH in 177 men 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 subjects 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. Men were excluded if they were 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 patients 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 men 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 Ottaiano literature review above, 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 patients with BPH were randomly assigned (2:1 ratio) to either aquablation or TURP. Patients 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). Patients (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 subjects 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.

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 men with large prostate compared with the overall result. Postoperative anejaculation was also less common after aquablation compared with TURP in sexually active men with large prostates vs. the overall results. Exploratory analysis showed larger IPSS changes after aquablation in men with enlarged middle lobes, men with severe middle lobe obstruction, men with a low baseline maximum urinary flow rate, and men with elevated post-void residual urine volume. The authors concluded that in men 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. (2018 - included in the 2022 Ottaiano literature review above) conducted a double-blind, multicenter, prospective, randomized, controlled trial (WATER I) to compare safety and efficacy of aquablation and TURP for the treatment of lower urinary tract symptoms related to benign prostatic hyperplasia. One hundred and eighty-one patients with moderate to severe lower urinary tract symptoms related to benign prostatic hyperplasia underwent transurethral prostate resection or aquablation. The primary efficacy end point was the reduction in International Prostate Symptom Score at 6 months. The primary safety end point was the development of Clavien-Dindo persistent grade 1, or 2 or higher operative complications. The results showed the mean total operative time was similar for aquablation and transurethral prostate resection, but resection time was lower for aquablation. At month 6 patients treated with aquablation and transurethral prostate resection experienced large I-PSS improvements. The prespecified study noninferiority hypothesis was satisfied. Of the patients who underwent aquablation and transurethral prostate resection 26% and 42%, respectively, experienced a primary safety end point, which met the study primary noninferiority safety hypothesis and subsequently demonstrated superiority. Among sexually active men the rate of anejaculation was lower in those treated with aquablation (10% vs. 36%) The authors concluded that surgical prostate resection using aquablation showed noninferior symptom relief compared to transurethral prostate resection but with a lower risk of sexual dysfunction. Larger prostates (50 to 80 ml) demonstrated a more pronounced superior safety and efficacy benefit. Longer term follow-up would help assess the clinical value of aquablation. This study was supported by PROCEPT Bio Robotics, the manufacturer of the AquaBeam® device. Several of the authors indicate a financial interest and/or other relationship with PROCEPT BioRobotics. These conflicts of interest may limit the conclusions that can be drawn from the study.

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 men 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 at 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.

Transperineal Placement of Biodegradable Material

Mariados et al. (2023) conducted a randomized, patient blinded clinical trial to evaluate whether a hyaluronic acid perirectal spacer can improve rectal dosimetry and affect acute grade 2 or higher GI toxicity for hypofractionated radiation therapy (HFRT) for prostate cancer. Patients with biopsy proven T1 to T2 prostate cancer with a Gleason score of 7 or less and a PSA of 20 ng/mL or less were included. Two hundred and one participants were randomly assigned 2:1 to receive either HA spacer plus fiducial markers (136) followed by HFRT (spacer group) or fiducial markers only (65) followed by HFRT (control group). 63 of the participants received androgen depravation therapy (ADT). The results showed that in the treatment group, 131 (98.5%) showed at least a 25% reduction in rectum V54 which was significantly higher than the 70% acceptable primary endpoint. The mean reduction was 85%. There were reductions in all protocol rectal dose volume histogram (DVH) metrics that included bladder, penile bulb and rectum. Four patients experienced grade 2 or higher GI toxicity. In the control group, 9 patients experience grade 2 or higher GI toxicity (difference, −10.9%; 95%1-sided upper confidence limit, −3.5; p = .01). The authors concluded that rectal spacing using a hyaluronic acid based device improves rectal dosimetry thereby reducing grade 2 or higher GI toxicity. Further research with longer follow up will validate these findings.

A Hayes health technology assessment (2021, updated in 2023) summarized that while published evidence suggests a potential benefit of an absorbable perirectal spacer (APS) during radiation therapy for prostate cancer, compared with no spacer, there is uncertainty regarding its safety and efficacy, chiefly due to conflicting results related to efficacy and global improvement, especially when compared with balloon rectal displacement devices and other spacers. Future studies are needed to assess the clinical usefulness and cost-effectiveness of an APS.

In a custom product brief, ECRI (2020) concludes that SpaceOAR hydrogel is well tolerated and works as intended to reduce rectal irradiation long-term, but not acute, rectal toxicity, and it improves bowel quality of life (QOL), based on one randomized controlled trial and four prospective nonrandomized comparative studies.

Afkhami Ardekani and Ghaffari (2020) evaluated the effect of dosimetry and procedure toxicity of polyethylene glycol (PEG)-based hydrogel spacers during prostate brachytherapy. There were twelve studies included in the systematic review involving 615 patients. The approach used to place the hydrogel spacers was hydrodissection and considered one of the most common techniques. Ultrasonography is used to insert a large gauge needle where saline water is injected to create potential space between the prostate and anterior rectal wall; PEG hydrogel is then injected into the created space. The DuraSeal and SpaceOAR then polymerize within 3 and 10 seconds after injection. The authors found the data of several studies revealed the rectal dosimetry was significantly reduced with the use of the PEG hydrogel spacers and that the procedure was safe. The authors concluded the implantation of PEG hydrogel spacers is practical and safe with well tolerance of the procedure. The use of PEG hydrogels for prostate brachytherapy has a very high success rate, however, the advantages of these spacers should be weighed against possible risks of complications. Additional RCTs should be done to further clarify rectal dose reduction on toxicity and quality of life.

A systematic review was conducted by Vaggers et al. (2020) from nine full text articles reviewing polyethylene glycol-based hydrogel rectal spacers for prostate brachytherapy. Four studies used the DuraSeal Spinal Sealant and five studies used SpaceOAR. Primary outcomes included procedure complications, failures, prostate-rectum separation, rectal dosimetry and GI toxicities for hydrogel insertion. There was little variation in technique used throughout the articles reviewed. The authors found the studies demonstrated a significant reduction in rectal dosimetry and concluded that the polyethylene glycol-based hydrogel rectal spacers appear to be safe and easy. Even though the spaces appear to reduce rectal toxicity, further studies are needed to confirm these findings. Limitations include the review as retrospective and non-randomization along with small sample size.

Wu et al. [2018, included in Afkhami Ardekani and Ghaffari (2020) and Vaggers et al. (2020) systematic reviews above] evaluated 18 consecutive patients underwent transperineal ultrasound-guided placement of 10 cc of SpaceOAR hydrogel prior to HDR brachytherapy in the treatment of prostate cancer. Treatment plans were generated using an inverse planning simulated annealing algorithm. Rectal dosimetry for these 18 patients was compared with the 36 preceding patients treated with HDR brachytherapy without SpaceOAR. There was no difference in age, pretreatment prostate-specific antigen, Gleason score, clinical stage, prostate volume, or contoured rectal volume between those who received SpaceOAR and those who did not. Patients who received SpaceOAR hydrogel had significantly lower dose to the rectum as measured by percent of contoured organ at risk (median, V80 < 0.005% vs. 0.010%, p = 0.003; V75 < 0.005% vs. 0.14%, p < 0.0005; V70 0.09% vs. 0.88%, p < 0.0005; V60 = 1.16% vs. 3.08%, p < 0.0005); similar results were seen for rectal volume in cubic centimeters. One patient who received SpaceOAR developed a perineal abscess 1 month after treatment. The authors concluded that transperineal insertion of SpaceOAR hydrogel at the time of HDR brachytherapy is feasible and decreases rectal radiation dose. Further investigation is needed with well-designed clinical trials and larger patient populations to further assess the clinical impact.

Taggar et al. [2018, included in Afkhami Ardekani and Ghaffari (2020) and Vaggers et al. (2020) systematic review above] conducted a prospective cohort study to evaluate placement of an absorbable rectal hydrogel spacer in 74 patients with prostate cancer undergoing low-dose-rate brachytherapy with palladium-103. Rectal dosimetry was compared with a consecutive cohort of 136 patients treated with seed implantation without a spacer. On average, 11.2 mm (SD 3.3) separation was achieved between the prostate and the rectum. The resultant mean rectal volume receiving 100% of prescribed dose (V100%), dose to 1 cc of rectum (D1cc), and dose to 2 cc of rectum (D2cc) were 0 (SD 0.05 cc), 25.3% (SD 12.7), and 20.5% (SD 9.9), respectively. All rectal dosimetric parameters improved significantly for the cohort with spacer placement as compared with the non-spacer cohort. Injection of rectal spacer is feasible in the post-LDR brachytherapy setting and reduces dose to the rectum with minimal toxicity. Prostate and urethral dosimetries do not appear to be affected by the placement of a spacer.

Pinkawa et al. (2017a) reported 5-year outcomes of a cohort study after prostate cancer radiation therapy with and without the use of a hydrogel spacer. Fifty-four patients were selected to receive a hydrogel spacer. Patients were surveyed before RT; at the last day of RT; and a median time of 2 months, 17 months, and 63 months after RT. For patients treated with a hydrogel spacer, mean bowel function and bother score changes of > 5 points in comparison with baseline levels were found only at the end of RT (10-15 points; $p < .01$). No patient with spacer reported moderate or big problems with their bowel habits overall. Mean bother score changes of 21 points at the end of RT, 8 points at 2 months, 7 points at 17 months, and 6 points at 63 months after RT were found for patients treated without a spacer. A bowel bother score change > 10 points was found in 6% versus 32% ($p < .01$) at 17 months and in 5% versus 14% ($p = .2$) at 63 months with versus without a spacer. The authors conclude that hydrogel spacer application demonstrates excellent treatment tolerability, in particular regarding bowel problems. They encourage further studies with dose-escalated or re-irradiation concepts.

Pinkawa et al. (2017b) evaluated in a cohort study of 167 consecutive patients who received prostate RT with 2 Gy fractions up to 76 Gy (without hydrogel, n = 66) or 76-80 Gy (with hydrogel, n = 101). The numbers of interventions resulting from bowel problems during the first 2 years after RT were compared. Patients were surveyed prospectively before RT, at the last day of RT, and at a median of 2 and 17 months after RT using a validated questionnaire (Expanded Prostate Cancer Index Composite). Treatment for bowel symptoms (0 vs. 11 %; $p < 0.01$) and endoscopic examinations (3 vs. 19 %; $p < 0.01$) were performed less frequently with a spacer. Mean bowel function scores did not change for patients with a spacer in contrast to patients without a spacer (mean decrease of 5 points) > 1 year after RT in comparison to baseline, with 0 vs. 12% reporting a new moderate/big problem with passing stools ($p < 0.01$). It was noted that statistically significant differences were found for the items "loose stools", "bloody stools", "painful bowel movements" and "frequency of bowel movements". The authors concluded that spacer injection is associated with a significant benefit for patients after prostate cancer RT.

Hamstra et al. (2017) reported the final outcomes from their single-blind phase III trial of image guided intensity modulated radiation therapy (n = 222). The 3-year incidence of grade ≥ 1 (9.2% vs. 2.0%; $p = .028$) and grade ≥ 2 (5.7% vs. 0%; $p = .012$) rectal toxicity favored the spacer arm. Grade ≥ 1 urinary incontinence was also lower in the spacer arm (15% vs. 4%; $p = .046$), with no difference in grade ≥ 2 urinary toxicity (7% vs. 7%; $p = 0.7$). From 6 months onward, bowel QOL consistently favored the spacer group ($p = .002$), with the difference at 3 years (5.8 points; $p < .05$) meeting the threshold for a MID. The authors reported that the benefit of a hydrogel spacer in reducing the rectal dose, toxicity, and QOL declines after image guided intensity modulated radiation therapy for prostate cancer was maintained or increased with a longer follow-up period, providing stronger evidence for the benefit of hydrogel spacer use in prostate radiation therapy. Additional long-term outcomes are needed to determine the benefits of hydrogel spacers.

In a prospective, randomized, patient-blinded clinical study, Karsh et al. (2017) compared image-guided intensity modulated prostate radiotherapy (79.2 Gy in 44 fractions) in men with or without insertion of prostate-rectum hydrogel spacer (SpaceOAR). The mean additional space created between the prostate and the rectum was just over 1 cm, which allowed significant rectum and penile bulb radiation dose reduction resulting in less acute pain, lower rates of late rectal toxicity, and improved bowel and urinary QOL scores from 6 months through the 3-year follow-up period as compared to the control group. The authors concluded that spacer application significantly reduced rectal radiation dose, resulting in long-term reductions in rectal toxicity, as well as improvements in bowel, urinary, and sexual QOL.

Yeh et al. [2016, included in Afkhami Ardekani and Ghaffari (2020) and Vaggers et al. (2020) systematic reviews above] studied rectal toxicity rates in 326 patients administered a polyethylene glycol (PEG) hydrogel rectal spacer in conjunction with combination high-dose-rate brachytherapy at 16 Gy [average dose 15.5 Gy; standard deviation (SD) = 1.6 Gy] and external beam radiotherapy of 59.4 Gy (average dose 60.2 Gy; SD = 2.9 Gy). Clinical efficacy was determined by measuring acute and chronic rectal toxicity using the National Cancer Center Institute Common Terminology Criteria for Adverse Events v4.0 grading scheme. Median follow-up was 16 months. The mean anterior-posterior separation achieved was 1.6 cm (SD = 0.4 cm). Rates of acute Grade 1 and 2 rectal toxicity were 37.4% and 2.8%, respectively. There were no acute Grade 3/4 toxicities. Rates of late Grade 1, 2, and 3 rectal toxicity were 12.7%, 1.4%, and 0.7%, respectively. There were no late Grade 4 toxicities. The authors concluded that acute and chronic rectal toxicities are low despite aggressive dose escalation. Longer term outcomes are needed to evaluate impact.

Mariados et al. (2015) conducted a prospective, multicenter, randomized controlled pivotal trial to assess outcomes following absorbable spacer (SpaceOAR system) implantation. The study included 222 patients with clinical stage T1 or T2 prostate cancer who underwent computed tomography (CT) and magnetic resonance imaging (MRI) scans for treatment planning, followed with fiducial marker placement. Patients were randomized to receive spacer injection or no injection (control). Spacer safety and impact on rectal irradiation, toxicity, and QOL were assessed throughout 15 months. Spacer application had a 99% hydrogel placement success rate. The authors reported that there were no device-related AEs, rectal perforations, serious bleeding, or infections within either group. Overall acute rectal adverse event rates were similar between groups, with fewer spacer patients experiencing rectal pain (p = .02). There was no late rectal toxicity greater than grade 1 in the spacer group. At 15 months 11.6% and 21.4% of spacer and control patients, respectively, experienced 10-point declines in bowel QOL. MRI scans at 12 months verified spacer absorption. The authors concluded that spacer application was well tolerated. Increased perirectal space reduced rectal irradiation, reduced rectal toxicity severity, and decreased rates of patients experiencing declines in bowel QOL. The spacer appears to be an effective tool, potentially enabling advanced prostate radiation therapy protocols. However, the short follow-up period is a study limitation, as researchers have published the median time to late gastrointestinal grade > 2 toxicity onset was 17 months. The study was also limited by the exclusion of patients with prostate volumes > 80 mL, patients with extracapsular extension, and those with prior radiation or surgery. Patients with extracapsular extension have the theoretical risk of pushing posterior extracapsular disease farther from the prostate during radiation therapy, whereas patients with prior radiation or surgery may have perirectal scar formation, limiting space creation. The authors noted that the use of spacers in these populations should proceed cautiously in separate clinical trials.

Prostate Artery Embolization (PAE)

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.

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.

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. 10 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 preprocedure 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 3.6 ng/mL. Both groups experienced similar symptomatic improvement at the 24-month follow-up, with no significant difference in objective measurements of urinary retention and LUTSs. The authors concluded that PAE is a safe and effective treatment for even large volume prostates, especially in 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 6 RCTs and 2 non-randomized studies (NRSs) evaluating short-term follow-up and 2 RCTs and 1 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 patients. The following comparisons were identified: 4 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 patients 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 28 patients over the age of 80 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 25 patients, and 2 received unilateral PAE. The results showed technical success with PAE in 27 of the 28 participants. All of the functional outcome's results were significantly improved at 12 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 2 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 2 years due to unsatisfactory results. The authors concluded that PAE for the treatment of BPH remains investigational due to inferior functional outcomes and a relevant re-treatment rate found 2 years after PAE compared with TURP. These disadvantages should be considered for patient selection and counselling.

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 men with severe LUTS refractory to medical management with alpha blockers. Following catheterization of a prostatic artery, eighty patients ≥ 45 years of age were randomized 1:1 to receive PAE or the sham procedure of no embolization. Primary outcomes were assessed at 6 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%) patients were still taking medication at the end of the main study, compared with only two (5.13%) in the PAE group. Regarding adverse events, 16 occurred in the PAE group, and 17 in the sham group. These included pain, bruising, hematospermia, hematuria and 3 patients experienced Inguinal hematoma. Two patients with dysuria and burning urethral pain, and one urinary tract infection were medically managed. One patient 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 5 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 patients were included, and all had imaging and cystoscopy to confirm the prostatic origin of hematuria. Following embolization, the participants were followed at 3,12, and 18 months using QoL, IPSS IIEF and clinical review. The results showed that bilateral PAE was technically successful in all 12 patients. At 3 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 patients 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 30 catheter dependent patients with large prostate volumes and high comorbidity scores. All patients presented with urinary retention and underwent PAE following at least two attempts at voiding without catheterization, and all had received prior pharmacological treatment. 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 3, 6, and 12 months. The results showed embolization was clinically successful in 26 patients, The mean time to catheter discontinuation was 18 days and these patients were catheter free at 3 months follow up. Additional follow up of 24 patients at 6 months and 17 patients at 12 months showed none required reintroduction of catheterization, and IPSS and QoL improved significantly from baseline. At 3 month follow up, 23 patients had discontinued all use of medications. Grade I complications occurred in 12 patients and predominantly consisted of hematuria, and all were resolved with the use of urinary analgesics or antimuscarinic medications. The author concluded that PAE is a safe and effective treatment for patients who are not surgical candidates, with clinical benefit lasting at least 12 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) conducted a randomized, open label, non-inferiority trial in the urology and radiology departments of a Swiss tertiary care center. 103 patients 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. 48 and 51 patients reached the primary endpoint 12 weeks after PAE and TURP, respectively. Primary outcome was change in international prostate symptoms score (IPSS) from baseline to 12 weeks after surgery (a difference of less than 3 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 12 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). (This trial was included in the systematic review by Xiang et al., 2021, and Sajan et.al., 2022).

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. 40 patients 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 patient had oncologic comorbidities including multiple myeloma, leukemia, prior prostate cancer, as well as colorectal, lung skin and bone cancers. Additionally, 4 patients had a pacemaker and 3 were on anticoagulation medication that could not be discontinued. Twenty patients were not eligible for uroflowmetry due to continued IBC or poor clinical status. Bilateral embolization was achieved in one procedure for 30 patients and 2 patients required a second procedure. Unilateral embolization was performed in 8 patients and the procedure was aborted in 2 patients due to hypogastric prostate artery stenosis. The mean follow-up time was 13 months. At 6 month follow up, the results showed prostate size and IPSS score reduction. Clavien II complications were reported in 9 patients. For 9 patients, this included UTI, episodes of acute urinary retention requiring temporary IDC placement. Nine patients experienced post embolization syndrome in the 48 hours following the procedure. The results showed that IBC removal was achieved in 33 patients at follow up. It was concluded that PAE is a safe and efficacious procedure in the elderly 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 1,3 and 9 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 22 patients, and no procedural complications were experienced. In the first month of follow-up, 15 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 9 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

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. The quality of the evidence is however insufficient to support the efficacy and safety of this technology.

Bates et al. (2021) conducted a systematic review (SR) to compare the clinical effectiveness of primary focal ablative therapy (FT) to standard current treatment options for clinically localized prostate cancer (PCa) to make clinical practice recommendations, and identify gaps, providing recommendations for further research. Four primary studies [1 randomized controlled trial (RCT) and 3 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 found PDT was associated with a significantly lower rate of treatment failure at 2 years, no difference in functional outcomes, and was associated with worse transient adverse events. A retrospective matched-pair study comparing focal high-intensity focused ultrasound (HIFU) with robotic radical prostatectomy (RP) found no significant differences in treatment failure at 3 years, while the focal HIFU group had better recovery of continence and erectile function. 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. 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 patients undergoing focal therapy were selected. Thirteen reported on high-intensity focused ultrasound, 11 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 4 months and 61 months, and the median rate of serious adverse events ranged between 0% and 10.6%. Pad free leak-free continence and potency were obtained in 83.3-100% 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 genito-urinary 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)

Transperineal laser ablation (TPLA) is a new minimally invasive procedure that focuses on lower urinary tract symptoms (LUTS) in patients with BPH. Currently there is insufficient evidence regarding the long-term effectiveness and safety for the use of TPLA; additional well designed RCTs and comparative analyses are warranted.

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, (2 retrospective and 4 prospective) comprised of 287 patients 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 1,3, 6 and 12 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, 2 prostatic abscesses, 4 cases of hematuria, 1 case of orchitis, 3 experienced acute urinary retention and 6 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 patients aged 50 and over who are 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 1 year, with the first year Qmax values statistically significantly higher in the TURP group than in the TPLA group. IIEF-5 scores were similar in both groups and MSHQ scores did not change in the TPLA group but were significantly decreased 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 4 prospective and 2 retrospective before and after studies. The 4 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 1-, 3-, 6-, and/or 12-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 6-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

Temporary urethral stents are used to maintain urine flow and are for short-term use; they are commonly used in males with BPH. These temporary devices can be either removable or absorbable. The quality of the evidence is, however, insufficient to support the efficacy and safety of this technology.

Amparore et al. (2023) conducted a multi-site prospective single-arm study comprised of 81 participants and reported the long term (50-79) month results using a temporary implantable nitinol device (iTind) in men with BPH related LUTS. Criteria for inclusion were patients with BPH, and IPSS ≥ 10, Qmax ≤ 12, prostate volume < 75 mL and normal urinalysis, complete blood count and biochemistry. The functional outcomes, PVR, Qmax, IPSS and IPSS-QoL were assessed at 1, 3, 6 and 12 months, then annually up to 36 months. IPSS and IPSS-QoL were assessed beyond 48 months. 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. The results showed prompt and sustained improvements in IPSS scores and QoL for up to 48 months. There were low rates of complications and adverse events and included UTI, hematuria and postoperative pain. All of which occurred within 30 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. Furthermore, due to the COVID-19 pandemic, only 50% of participants were available for more than 48 months of follow up, and only subjective information was reported.

A Hayes (2022, updated in 2023) evolving evidence report identifies limited evidence and minimal support for the use of the iTind system. Current fair to poor quality studies show improvements in BPH may be inferior to other minimally invasive and surgical options.

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 with high risk of bias, therefore are inconclusive.

Chughai et al. (2020) conducted a RCT that compared a temporarily implanted nitinol device (iTind; aka ITIND or Tind) to that of a sham on 175 males with lower urinary tract symptoms due to benign prostatic hyperplasia (BPH). Inclusion criteria for the participants were males 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 patient 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 3 months. A total of 78.6% of patients in the iTind arm showed a reduction of ≥ 3 points in IPSS, vs. 60% of patients in the control arm at 3 months (p = .029). Adverse events occurred in 38.1% of patients 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 patients 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 3 and 6 weeks, and 3, 6, 12, 24 and 36 months after the implantation. The change from baseline in IPSS, QOL score and Qmax was significant at every follow-up time point. After 36 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.

Goh et al. (2013) assessed the ease of insertion and removal of a temporary prostatic stent (the Spanner) following the use of a prostatic urethral measuring device (the Surveyor™) in patients with bladder outflow obstruction or urinary retention awaiting definitive surgery. 16 patients had the Spanner inserted following use of the Surveyor. All insertions were uncomplicated. No symptomatic infection was reported. The stents stayed in situ for a median of 10 days. 12 stents were removed prematurely due to severe symptoms or retention. A total of 12 stents had to be removed endoscopically. The authors concluded that the Spanner is easy to insert. Stent removal via the retrieval suture has been difficult necessitating the use of endoscopy in the majority of cases. Possible causes of stent failure include underestimation of the prostatic urethral length by the surveyor leading to obstruction by apical prostatic tissue, excessive suture length between the stent and distal anchor permitting proximal migration or inadequate suture length leading to urinary incontinence. According to the authors, further design modifications are suggested.

Following transurethral microwave thermotherapy, 186 patients were randomized to receive a Spanner (n = 100) or the standard of care (n = 86). The stent group reported significantly superior improvement in symptoms at the one-week follow-up visit. Thereafter, there was no significant difference between the stent and control groups. The investigators concluded that the Spanner is a safe, effective and well tolerated temporary stent for severe prostatic obstruction resulting from therapy induced edema after transurethral microwave thermotherapy (Dineen et al., 2008). Shore et al. published the same study in 2007. The study results are limited in demonstrating meaningful improvement in clinical outcomes in the group that received the temporary prostatic stent compared to the patients in the control group.

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; additional robust RCTs with comparison groups along with long-term results are needed.

Johannsen et al. (2007) conducted a prospective phase I clinical trial in 10 men 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 7 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 60 min 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 5 thermotherapy sessions, not 6. 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 2-4 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 patient experienced worsening urinary urge and frequency due to a bladder neck contraction, Grade 3 urinary toxicity was noted in two patients, with both bladder spasms and urinary frequency grade 3 in one patient 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 patients. In one patient, 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 thermoablative 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

Transurethral drug coated balloons are a novel device being investigated for the treatment of LUTS due to BPH. There is insufficient evidence regarding the safety and efficacy of this device and additional robust RCTs with comparison groups and longer-term results are needed.

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® Catheter System) for the treatment of LUTS due to BPH. One hundred forty-eight men 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. After 3 month follow up, patients 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 14 days, 30 days, and 6 and 12 months in both arms and included self-assessments and subjective measurements of uroflowmetry and PVR. The results showed a reduction in IPSS of an average of 11.5 at one year, compared to an average of 8.0 in the sham arm at 3 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 patients in the treatment arm reported an adverse ejaculatory dysfunction compared to 1 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.

Clinical Practice Guidelines

American Urological Association (AUA)

In 2023, the AUA (Sandhu et al.) 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 from 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 2017 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 (Chang et al., 2017).

National Comprehensive Cancer Network (NCCN)

Clinical practice guidelines for the treatment of prostate cancer states "biocompatible and biodegradable perirectal spacer materials may be implanted between the prostate and rectum in patients undergoing external radiotherapy with organ-confined prostate cancer in order to displace the rectum from high radiation dose regions. Perirectal spacer materials may be employed when the other techniques are insufficient to improve oncologic curet rates and/or reduce side effects due to anatomic geometry or other patient related factors, such as medication usage and/or comorbid conditions. Patients with obvious rectal invasion or visible T3 and posterior extension should not undergo perirectal spacer implantation.

For 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.

For 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.

National Institute for Health and Care Excellence

The 2023 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 2023 NICE interventional procedures guidance on biodegradable spacer insertion to reduce rectal toxicity during radiotherapy for prostate cancer states that the evidence for this procedure is limited in quality and that the procedure should only be done with special arrangements for clinical governance, consent and audit or research.

A 2020 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 2018 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 October 20, 2023)

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 October 20, 2023)

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 October 20, 2023)

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) has cleared rectal spacer devices under its 510(k) Premarket Notification process. Refer to the following website for information using product code OVB: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed November 27, 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 October 20, 2023)

In December 2017, the FDA granted a De Novo request for the ITind system (Olympus America, Center Valley, PA) (DEN190020), a temporarily-placed system for the urethra to treat urinary symptoms associated with BPH. 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 23, 2022)

There are a number of ureteral stents cleared by the FDA under its 510(k) premarket notification process. Additional information can be found at the following website using product code FAD, or using the specific device name: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed November 14, 2023)

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 October 20, 2023)

In June 2017, the FDA granted a De Novo request for Embosphere® Microspheres (Merit Medical Systems, Jordan, UT) for embolization of prostatic arteries for symptomatic benign prostatic hyperplasia. Refer to the following website for additional information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN160040. (Accessed October 20, 2023)

For additional information on microsphere products with 510(k) premarket notification, refer to the following website and search by product code NOY: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed October 20, 2023)

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 October 20, 2023)

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 October 20, 2023)

References

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

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

Afkhami Ardekani M, Ghaffari H. Optimization of prostate brachytherapy techniques with polyethylene glycol-based hydrogel spacers: A systematic review. Brachytherapy. 2020 Jan-Feb;19(1):13-23.

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

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

American Urological Association. Clinically Localized Prostate Cancer: AUA/ASTRO Guideline 2022. Available at: https://www.auanet.org/guidelines-and-quality/guidelines/clinically-localized-prostate-cancer-aua/astro-guideline-2022. Accessed October 23, 2023.

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

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

Bhatia S, Sinha VK, Kava BR, et al. Efficacy of prostatic artery embolization for catheter-dependent patients with large prostate sizes and high comorbidity scores. J Vasc Interv Radiol. 2018 Jan;29(1):78-84.e1. doi: 10.1016/j.jvir.2017.08.022. Epub 2017 Nov 15.

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

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

Chang SS, Bochner BH, Chou R, et al. Treatment of non-metastatic muscle-Invasive bladder cancer: AUA/ASCO/ASTRO/SUO Guideline. J Urol. 2017 Sep;198(3):552-559.

Chin YF, Lynn N. Systematic review of focal and salvage cryotherapy for prostate cancer. Cureus. 2022 Jun 28;14(6):e26400. doi: 10.7759/cureus.26400.

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

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

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

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

ECRI Institute. Aquabeam Robotic System (Procept Biorobotics Corp.) for Treating Benign Prostatic Hyperplasia. Plymouth Meeting (PA): ECRI Institute; October 2018; updated September 2023.

ECRI Institute. Product Brief. UroLift System (NeoTract, Inc.) for treating benign prostatic hyperplasia. July 2019.

ECRI Institute. Custom Product Briefs Guidance. SpaceOAR System (Augmenix, Inc.) hydrogel spacer for reducing rectal exposure during radiation therapy for prostate cancer. February 2016. Updated February 2020.

ECRI Institute. Clinical Evidence Assessment. Transperineal Laser Ablation for Treating Benign Prostatic Hyperplasia. May 2022.

ECRI Institute. Clinical Evidence Assessment. iTind System (Olympus America, Inc.) for Treating Benign Prostatic Hyperplasia. March 2022. Updated March 2023.

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

European Association of Urology (EAU). Guidelines on Non-Neurogenic Male Lower Urinary Tract Symptoms (LUTS), incl. Benign Prostatic Obstruction (BPO). 2023. Available at: https://uroweb.org/guidelines. Accessed October 30, 2023.

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

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

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

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

Gilling P, Barber N, Bidair M, et al. A double-blind, randomized controlled trial of aquablation vs. transurethral resection of the prostate in benign prostatic hyperplasia. J Urol. 2018 May;199(5):1252-1261.

Gilling PJ, Barber N, Bidair M, et al. Randomized Controlled Trial of aquablation versus transurethral resection of the prostate in benign prostatic hyperplasia: One-year Outcomes. Urology. 2019; 125:169-173.

Goh MH, Kastner C, Khan S, et al. First experiences with the Spanner™ temporary prostatic stent for prostatic urethral obstruction. Urol Int. 2013;91(4):384-90.

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

Hamstra DA, Mariados N, Sylvester J, et al. Continued benefit to rectal separation for prostate radiation therapy: final results of a phase III trial. Int J Radiat Oncol Biol Phys. 2017 Apr 1;97(5):976-985.

Hayes, Inc. Evolving Evidence Review. iTind (Olympus) for Benign Prostatic Hyperplasia. Lansdale, PA: Hayes Inc.; March 2022. Updated May 2023.

Hayes, Inc. Health Technology Assessment. Prostatic urethral lift (UroLift System) for treatment of symptoms associated with benign prostatic hyperplasia. Lansdale, PA: Hayes Inc.; June 2020; amended August 2021. Updated July 2022.

Hayes, Inc. Aquablation for Treatment of Benign Prostatic Hyperplasia. Lansdale, PA: Hayes, Inc.; March 30, 2021; amended April 2021. Updated March 2023.

Hayes, Inc. Health Technology Assessment. Prostatic Artery Embolization for Treatment of Benign Prostatic Hyperplasia. April 2023.

Hayes, Inc. Health Technology Assessment. Absorbable perirectal spacer (SpaceOAR) System; Augmenix Inc.) during radiation therapy for prostate cancer. Lansdale, PA: Hayes, Inc., September 2021. Updated October 2023.

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

Hwang EC, Jung JH, Borofsky M, et al. Aquablation of the prostate for the treatment of lower urinary tract symptoms in men with benign prostatic hyperplasia. Cochrane Database Syst Rev. 2019;2(2):CD013143. Published 2019 Feb 13.

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

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

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

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

Kaplan SA, Moss J, Freedman S, et al. The PINNACLE Study: A double-blind, randomized, sham-controlled study evaluating the Optilume BPH Catheter System for the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia. J Urol. 2023 Sep;210(3):500-509.

Karsh LI, Gross ET, Pieczonka CM, et al. Absorbable hydrogel spacer use in prostate radiotherapy: a comprehensive review of phase 3 clinical trial published data. Urology. 2018 May;115:39-44.

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

Mariados N, Sylvester J, Shah D, et al. Hydrogel spacer prospective multicenter randomized controlled pivotal trial: dosimetric and clinical effects of perirectal spacer application in men undergoing prostate image guided intensity modulated radiation therapy. Int J Radiat Oncol Biol Phys. 2015 Aug 1;92(5):971-7.

Mariados NF, Orio PF 3rd, Schiffman Z, et al. Hyaluronic acid spacer for hypofractionated prostate radiation therapy: A Randomized Clinical Trial. JAMA Oncol. 2023 Apr 1;9(4):511-518.

McWilliams JP, Bilhim TA, Carnevale FC, et al. Society of Interventional Radiology Multi-society Consensus Position Statement on Prostatic Artery Embolization for Treatment of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: From the Society of Interventional Radiology, the Cardiovascular and Interventional Radiological Society of Europe, Société Française de Radiologie, and the British Society of Interventional Radiology: Endorsed by the Asia Pacific Society of Cardiovascular and Interventional Radiology, Canadian Association for Interventional Radiology, Chinese College of Interventionalists, Interventional Radiology Society of Australasia, Japanese Society of Interventional Radiology, and Korean Society of Interventional Radiology. J Vasc Interv Radiol. 2019 May;30(5):627-637.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Prostate Cancer, v4.2023. September 7, 2023.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Bladder Cancer, v3.2023. May 25, 2023.

National Institute for Health and Care Excellence (NICE). Interventional procedures guidance [IPG752]. Biodegradable spacer insertion to reduce rectal toxicity during radiotherapy for prostate cancer. February 2023.

National Institute for Health and Care Excellence (NICE). Interventional procedures guidance [IPG770]. Transurethral water-jet ablation for lower urinary tract symptoms caused by benign prostatic hyperplasia. April 2018.

National Institute for Health and Care Excellence (NICE). Medical technologies guidance [MTG49]. Rezum for treating lower urinary tract symptoms secondary to benign prostatic hyperplasia. September 2023.

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

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

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

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

Pinkawa M, Berneking V, Schlenter M, et al. Quality of life after radiation therapy for prostate cancer with a hydrogel spacer: 5-year results. Int J Radiat Oncol Biol Phys. 2017a;99(2):374-377.

Pinkawa M, Berneking V, Konig L, et al. Hydrogel injection reduces rectal toxicity after radiotherapy for localized prostate cancer. Strahlenther Onkol. 2017b;193(1):22-28.

Pisco JM, Bilhim T, Costa NV, et al. Randomised clinical trial of prostatic artery embolisation versus a sham procedure for benign prostatic hyperplasia. Eur Urol. 2020 Mar;77(3):354-362.

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

Porpiglia F, Fiori C, Bertolo R, et al. 3-Year follow-up of temporary implantable nitinol device implantation for the treatment of benign prostatic obstruction. BJU Int. 2018 Jul;122(1):106-112.

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

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

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

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

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

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

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

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

Taggar AS, Charas T, Cohen GN, et al. Placement of an absorbable rectal hydrogel spacer in patients undergoing low-dose-rate brachytherapy with palladium-103. Brachytherapy. 2018;17(2):251-258.

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

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

Vaggers S, Rai BP, Chedgy ECP, et al. Polyethylene glycol-based hydrogel rectal spacers for prostate brachytherapy: a systematic review with a focus on technique. World J Urol. 2020 Aug 25.

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

van Luijtelaar A, Greenwood BM, Ahmed HU, et al. Focal laser ablation as clinical treatment of prostate cancer: report from a Delphi consensus project. World J Urol. 2019 Oct;37(10):2147-2153.

Veyg D, Mohanka R, Rumball IP, et al. Comparison of 24-Month Clinical Outcomes after Prostatic Artery Embolization in Prostate Glands Larger versus Smaller than 80 mL: A Systematic Review. J Vasc Interv Radiol. 2023 Apr;34(4):578-584.e1.

Wu SY, Boreta L, Wu A, et al. Improved rectal dosimetry with the use of SpaceOAR during high dose-rate brachytherapy. Brachytherapy. 2018;17(2):259-264.

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

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

Yeh J, Lehrich B, Tran C, et al. Polyethylene glycol hydrogel rectal spacer implantation in patients with prostate cancer undergoing combination high-dose-rate brachytherapy and external beam radiotherapy. Brachytherapy. 2016 Feb 4. pii: S1538-4721(15) 00633-9.

Zumstein V, Betschart P, Vetterlein MW, et al. Prostatic Artery Embolization versus Standard Surgical Treatment for Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia: A Systematic Review and Meta-analysis. Eur Urol Focus. 2019 Nov;5(6):1091-1100.

Policy History/Revision Information

Date	Summary of Changes
06/01/2025	• New Medical Policy

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.

UnitedHealthcare uses InterQual® for the primary medical/surgical criteria, and the American Society of Addiction Medicine (ASAM) criteria for substance use disorder (SUD) services, in administering health benefits. If InterQual® does not have applicable criteria, UnitedHealthcare may also use UnitedHealthcare Medical Policies that have been approved by the Kansas Department of Health and Environment. The UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.