Prostate Surgeries and Interventions (for Indiana Only)

Policy Number: CS334IN.04
Effective Date: July 1, 2023

Instructions for Use

Table of Contents **Page**

Related Policies
None

Application

This Medical Policy only applies to the state of Indiana.

Coverage Rationale

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 of the prostate is medically necessary for prostate cancer under certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Cryoablation, Prostate. If medical necessity cannot be determined using these criteria, refer to InterQual® Medicare: Procedures, Minimally Invasive Surgery, Prostate.

Click here to view the InterQual® criteria.

Radical prostatectomy is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Prostatectomy, Radical.

Click here to view the InterQual® criteria.

Radical prostatectomy is proven and medically necessary in conjunction with a radical cystectomy for bladder cancer.

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 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 is unproven and not medically necessary due to insufficient evidence of safety and/or efficacy.

Transurethral waterjet ablation of the prostate is medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® Medicare: Procedures, Transurethral Waterjet Ablation of the Prostate.

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.

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)
- Vascular embolization
- Ablation of malignant prostate tissue by magnetic field induction

Applicable Codes

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

CPT Code	Description
*0421T	Transurethral waterjet ablation of prostate, including control of post-operative bleeding, including ultrasound guidance, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included when performed)
*0582T	Transurethral ablation of malignant prostate tissue by high-energy water vapor thermotherapy, including intraoperative imaging and needle guidance
*0655T	Transperineal focal laser ablation of malignant prostate tissue, including transrectal imaging guidance, with MR-fused images or other enhanced ultrasound

CPT Code	Description
*0714T	Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance
*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
*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
55866	Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed
55867	Laparoscopy, surgical prostatectomy, simple subtotal (including control of postoperative bleeding, vasectomy, meatotomy, urethral calibration and/or dilation, and internal urethrotomy), includes robotic assistance, when performed
*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

Note: Codes labeled with an asterisk (*) are not managed for medical necessity review for the state of Indiana at the time this policy became effective. Refer to the most up to date prior authorization list for Indiana at Prior Authorization and Notification: UnitedHealthcare Community Plan of Indiana.

Description of Services

Benign prostatic hyperplasia (BPH) is an enlarged prostate and occurs most often during the second growth phase of the prostate (around age 25 and up). As the prostate enlarges, it presses against the urethra, which can result in the thickening of the bladder wall, the inability to empty the bladder fully, trouble starting urination, a week flow, urgency and needing to push or strain to urinate. In most men, BPH gets worse with age and can lead to bladder and kidney damage and infection.

Several procedures have been proposed for treatment of BPH including transurethral resection of the prostate (TURP), laser vaporization or enucleation, transurethral microwave therapy, transurethral needle ablation, waterjet ablation, thermotherapy, prostatic arterial embolization, prostatectomy, prosthetic stents, transurethral incision of the prostate transurethral microwave therapy (TUMT), transurethral holmium laser ablation (HoLAP), and prostatic urethral lift (PUL) (Hayes, Inc., 2020).

Minimally invasive surgical treatments (MISTs) are options to relieve symptoms of BPH while minimizing hospitalizations and complications of other treatments. One of these MISTs is the Rezūm™ System which 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, the Aquabeam® Robotic System which uses a heat-free water jet for the ablation of benign prostate tissue.

Transperineal laser ablation (TPLA) is a minimally invasive procedure intended to ablate prostate tissue using heat from a low-powered laser which is delivered via an optical fiber inserted through the patient's perineal skin and into the prostate. The intent of TPLA is to relieve lower urinary tract symptoms in patients with BPH. A surgeon performs the procedure under local or general anesthesia using a transrectal ultrasound for guidance and inserts thin needles into the targeted area of the prostate. An optical fiber is then inserted and delivers heat which destroys the prostate tissue (ECRI, 2022).

Aquablation is performed by a medical device that allows rapid removal of prostate tissue without leaving a zone of thermal damage on the treated tissue. It utilizes a waterjet for automated tissue resection as well as for optical energy delivery for cauterization in the treatment of BPH (Hayes, 2018).In PUL, permanent UroLift® implants are placed to hold open the lateral lobes of the prostate in a minimally invasive procedure to reduce urinary obstruction (Roerborn et al., 2017).

Embolization places medications or synthetic materials through a catheter into a blood vessel to block blood flow to an area of the body. It may be used to control or prevent abnormal bleeding, close off vessels supplying blood to a tumor, eliminate abnormal connections between arteries and veins, or to treat aneurysms. When performed for the prostate in patients with benign prostatic hyperplasia (BPH), microspheres are injected into the prostate blood vessels, 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).

Prostate cancer can be treated by surgery, medications, and/or radiotherapy. Transperineal placement of biodegradable material is sometimes used to protect other pelvic structures during radiotherapy.

Clinical Evidence

Prostatic Urethral Lift (PUL)

In 2017, Roehrborn et al. published five-year outcomes of the prospective, multi-center, 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.

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

The SpaceOAR is used to temporarily position the anterior rectal wall away from the prostate during radiotherapy for prostate cancer and in creating this space it is the intent to reduce the radiation dose delivered to the anterior rectum. The absorbable spacer maintains space for the entire course of prostate radiotherapy treatment and is completely absorbed by the patient's body over time.

A Hayes health technology assessment (2021, updated in 2022) 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 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.

Paetkau et al. (2019) retrospectively evaluated 13 patients with SpaceOAR implant to determine future planning needs for patients with prostate cancer undergoing radiation therapy. Computerized tomography (CT) scans were taken pre- and post-implant. A prescription of 60 Gy in 20 fractions was planned on both scans. Six treatment plans were produced per anonymized dataset using either a structure of rectum plus the hydrogel, termed composite rectum wall (CRW), or rectal wall (RW) as an inverse optimization structure and intensity modulated radiotherapy (IMRT) or volumetric modulated arc therapy (VMAT) as a treatment technique. Dose-volume histogram metrics were compared between plans to determine which optimization structure and treatment technique offered the maximum rectal dose sparing. RW structures offered a statistically significant decrease in rectal dose over CRW structures, whereas the treatment technique (IMRT vs VMAT) did not significantly affect the rectal dose. There was improvement seen in bladder and penile bulb dose when VMAT was used as a treatment technique. The authors concluded that overall, treatment plans using the RW optimization structure offered the lowest rectal dose while VMAT treatment technique offered the lowest bladder and penile bulb dose.

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.

Chao et al. (2018) conducted a prospective case series analysis to report on the dosimetric benefits and late toxicity outcomes following injection of a hydrogel spacer between the prostate and rectum in 76 patients with T1-T3a prostate cancer treated with radiotherapy. There were no postoperative complications reported. Mean prostate size were 66.0cc (25.0cc - 187.0cc). Rectal dose volume parameters were observed with volume of rectum receiving 70Gy (rV70), 75Gy (rV75) and 78Gy (rV78) were 7.8%, 3.6% and 0.4%. 21% (16/76) developed acute grade 1 GI toxicities but all were resolved completely by 3 months post-treatment. 3% (2/76) developed late grade 1 GI toxicities. No patients experienced acute or late grade 2+ GI toxicities. The authors concluded that injection of hydrogel spacer resulted in a reduction of irradiated rectal dose volumes along with minimal GI toxicities, irrespective of prostate size. Additional studies with longer-term outcomes are needed to evaluate long-term toxicities. The findings are limited by lack of comparison group.

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 spacer patient reported moderate or big problems with his 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 control group

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 (79.2Gy 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 1cm, 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.

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 prostate cancer (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 3230 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%. Padfree 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 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.

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.

De Reinzo et al. (2021), conducted a case series which prospectively analyzed patients that underwent TPLA of the prostate. Inclusion criteria were presence of moderate to severe lower urinary tract symptoms (LUTS) due to benign prostatic obstruction (BPO) with an International Prostate Symptom Score (IPSS) ≥ 12, aged 40 – 90 years, with prostate volume up to 100 ml and lack of efficacy, and intolerance or poor compliance to medical therapies. Twenty-one patients were included in this study sixteen of which had received at least one oral medication and five had refused medical treatment. Patients were discharged within 24 hours of procedure and kept the transurethral catheter for 8.7 ±2.5d. The authors found all but one patient was able to discontinue medical therapy within one month showing improvement in Qmax and IPSS scores which continued to improve at 6 months. Ejaculatory function was preserved and only one patient complication (prostatic abscess) was noted. Limitations included the absence of a control group, small sample size, and heterogeneity among patients with previous medical therapy.

Pacella et al. (2020, included in the ECRI report cite above) conducted a multicenter retrospective case series to assess the effectiveness and safety of TPLA in the treatment of patients with symptomatic BPH. The primary endpoints were evaluation of IPSS, QoL, Qmax, PVR, and prostatic volume at 6- and 12-months post TPLA treatment with secondary end-point evaluation of complications. Prior to treatment, patients completed the IPSS and QoL questionnaires, completed urodynamics to evaluate Qmax, had an abdominal ultrasound to determine post voiding residual (PVR), and transrectal ultrasound to evaluate volume of the prostate. There were 160 patients included with a follow-up of at least 6 months and 83 patients with a follow-up of at least 12 months. At both 6 and 12 months, the authors noted improvement of IPSS, PVR, Qmax, QoL and volume. Out of 160 cases, there were 7 grade I complications including hematuria, acute urinary retention and one orchitis, along with 1 grade III complication which was a prostatic abscess. Limitations included retrospective analysis with no other treatment comparison, treatment in separate centers with potential effect to the results related to operator experience with a novel technique, only a select subgroup of patients with minimum of 6 months of follow-up data were included, and ejaculatory function was not evaluated in the questionnaire and might be underestimated in this study.

Clinical trials for TPLA are currently ongoing. Refer to the following website for more information: https://clinicaltrials.gov/ct2/home (Accessed February 10, 2023).

Temporary Urethral Stents

Temporary urethral stents are used to maintain urine flow and 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.

A Hayes (2022) evolving evidence report identifies limited evidence and weak support for the use of the iTind system; it is currently under investigation for its use in treatment of lower urinary tract symptoms for BPH.

Ahn et al. (2020) retrospectively investigated the clinical effectiveness between two temporary urethral stents in the treatment of traumatic bulbar urethral strictures. 30 patients diagnosed with complete bulbar urethral rupture following blunt trauma underwent temporary urethral stent placement. Fifteen patients were treated with a thermo-expandable nickel-titanium alloy urethral stent (Memokath) and the other fifteen with the Allium Bulbar Urethral Stent (BUS). After placement, all stents were removed at 6 months with participant follow up at 1, 3, 6 and 12 months. The follow-up visits included patient assessment with uroflowmetry and ureteroscopy. While the BUS had a lower incidence of stent-related complications than Memokaths, the authors concluded both stents were effective for managing traumatic complete bulbar urethral rupture. This review is limited by lack of randomization, lack of comparison group undergoing traditional open urethroplasty, small sample size and short duration of follow-up; further investigation is warranted.

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.

Kimata et al. (2015) conducted a small prospective case series (n = 37 elderly male patients) to evaluate the use of the Memokath in patients who required long-term urination management with Foley catheters. Patients were followed for a mean of approximately 33 months. A total of 21 patients (56.7%) were able to urinate without assistance after insertion of the Memokath stent. This study was hampered by several limitations, including lack of randomization and appropriate control group.

Kim et al. (2014) conducted a small cohort study (n = 27) to compare patients who received treatment with a Memokath stent and a self-expandable covered metallic stent (UVENTA) for managing ureteral obstructions. Study results showed no significant differences between the two types of stents for benign and malignant ureteral obstructions. However, the clinical success rate was higher for the UVENTA stent (82.4%) compared with the Memokath stent (42.9%) (p = 0.031). Patients who received the Memokath stent experienced tumor progression (n = 2), stent migration (n = 6), flank pain (n = 1), and acute pyelonephritis (n = 1). The study is limited by lack of comparison with other established treatments or randomization between the two stent types.

Jordan et al. (2013) investigated the ability of the Memokath™ 044TW stent to maintain urethral patency after dilation or internal urethrotomy for recurrent urethral stricture. A total of 92 patients with recurrent bulbar urethral strictures were treated with dilation or internal urethrotomy and randomized to short-term urethral catheter diversion (n = 29) or insertion of a Memokath 044TW stent (n = 63). The primary end point was urethral patency, as assessed by passage of a calibrated endoscope. Secondary end points included urinary symptoms and uroflowmetry parameters. Stents were scheduled to remain in situ for 12 months. The rate of successful stent insertion was 93.6%. In stented patients, patency was maintained significantly longer than controls (median 292 vs 84 days). Patency was reflected in significantly improved uroflowmetry and symptom scores. The stent was removed in 100% of patients. The most frequently noted side effects in stented patients were bacteriuria, hematuria and penile pain, which were usually mild and transient. Stent dislocation and occlusion were observed in 8 and 3 patients, respectively. The authors concluded that patients with recurrent bulbar urethral strictures treated with dilation or urethrotomy and a Memokath 044TW stent maintained urethral patency significantly longer than those treated with dilation or urethrotomy alone. The Memokath stent is not FDA approved and should be considered investigational. Based on differences in stent design, these findings may not be generalizable to FDA-approved devices.

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.

For information on current and completed trials studying the use of temporary prostatic urethral stents refer to ClinicalTrials.gov. (Accessed February 10, 2023)

Prostate Artery Embolization (PAE)

Evidence from several randomized controlled trials show inconclusive findings or inferiority of prostate artery embolization as compared to established treatments for effectiveness, with some apparent benefit for adverse events. Therefore, the evidence is currently insufficient to consider this technology to be proven as non-inferior or superior to established approaches.

In a Cochrane review, Jung et al. (2022) completed a systematic review of literature to assess the effects of prostatic arterial embolization (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 outcomes 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.

In a 2019 Hayes health technology assessment, updated in 2022, regarding prostatic artery embolization (PAE) for the treatment of benign prostatic hypertrophy (BPH), it was concluded that based on a moderately large body of evidence, and low quality due to individual study limitations, PAE is reasonable safe, but long-term efficacy has not been adequately evaluated. The overall conclusion of the report is that there is potential but unproven benefit of this technology.

In a 2019 systematic review and meta-analysis, 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.

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).

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.

Clinical Practice Guidelines

American Urological Association (AUA)

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

- PUL may be offered as an option for patients with LUTS attributed to BPH provided prostate volume < 80g 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).
- Aquablation may be offered to patients provided prostate volume > 30/< 80g. (Conditional Recommendation; Evidence Level: Grade C)
- Water vapor thermal therapy:
    - May be offered to patients with LUTS/BPH with a prostate volume of < 80g. patients should be informed that evidence of efficacy, including longer-term retreatment rates, remains limited. (Conditional Recommendation; Evidence Level: Grade C)
    - Patients who desire preservation of erectile and ejaculatory function (Conditional Recommendation; Evidence Level: Grade C)

- Prostate artery embolization is not recommended for the treatment of LUTS/BPH outside the context of a clinical trial until sufficient evidence from rigorous studies is available that show benefit over well-established therapies (Expert Opinion)

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. (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), the American Society of Clinical Oncology (ASCO), the American Society for Radiation Oncology (ASTRO), and the 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).

The National Comprehensive Cancer Network (NCCN)

Clinical practice guidelines for the treatment of prostate cancer (v4.2022) 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: “Radical prostatectomy is appropriate for any patient whose cancer appears clinically localized to the prostate. However, because of potential perioperative morbidity, radical prostatectomy should generally be reserved for patients whose life expectancy is 10 years or more.” Radical proctectomy is listed as one of the options for some high or very high-risk patients, and some patients with cancer recurrence.

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

National Institute for Health and Care Excellence

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) in the NHS. 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 medical technology guidance on use of the Memokath-051 stent for ureteric obstruction concludes that the quality of reporting across all the studies was generally poor. None of the studies provided adequate details on patient characteristics, stent insertion procedures, follow-up, statistical analyses and uncertainty around the results. Migration rates and

clinical success were the most commonly reported outcomes, but definitions of clinical success varied, so statistical pooling could not be done.

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 cm3), 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. (McWilliams et al., 2019)

U.S. Food and Drug Administration (FDA)

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

Prostate surgeries are procedures and, therefore, not regulated by the FDA. However, devices and instruments used during the surgery may require FDA approval. Refer to the following website for additional information: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed November 23, 2022)

On September 13, 2013, the FDA approved the UroLift® System (Teleflex Inc., Pleasanton, CA) for marketing through a de novo classification as a class II device used as a permanent implant to relieve low or blocked urine flow in men with BPH. Since that time, additional FDA clearances have been granted. For additional information refer to the following, using the product code PEW: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K193269. (Accessed November 23, 2022)

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. For additional information, see: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K191505. (Accessed November 23, 2022)

The U.S. Food and Drug Administration (FDA) has cleared powered laser devices under 510(k) Premarket Notification. For device specific information, search product code GEX here: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm. (Accessed November 23, 2022)

The U.S. Food and Drug Administration (FDA) cleared SpaceOAR Vue hydrogel (Boston Scientific Corporation) (K182971) under its 510(k) premarket notification process as substantially equivalent to predicate devices on June 19, 2019. For additional information refer to the following: https://www.accessdata.fda.gov/cdrh_docs/pdf18/K182971.pdf. (Accessed November 23, 2022)

The U.S. Food and Drug Administration (FDA) approved the Spanner® Temporary Prostatic Stent (SRS Medical, North Billerica, MA) on December 14, 2006. Refer to the following website for additional information:

- https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma_template.cfm?id=p060010
- https://www.accessdata.fda.gov/cdrh_docs/pdf6/p060010a.pdf

(Accessed November 23, 2022)

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 (K210138). Refer to the following website for additional information:. https://www.accessdata.fda.gov/cdrh_docs/pdf21/K210138.pdf.
(Accessed November 23, 2022)

On March 3, 2021, the Aquabeam® Robotic System (Procept BioRobotics, Redwood City, CA) received 510(k) approval as a Class II device. Refer to the following for further information:
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K202961. (Accessed November 23, 2022)

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 November 23, 2022)

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 November 23, 2022)

The ECHOLASER X4 system received 510(k) Premarket Notification (K181510) from the FDA in September of 2018. The device is intended for use in cutting, vaporization, ablation and coagulation of soft tissue and in the treatment and/or removal of vascular lesions (tumors). For additional information, refer to the following website:
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed November 23, 2022)

The Memokath has not yet received FDA approval.

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.

Ahn ST, Lee DH, Kim JW, et al. Novel treatment strategy for management of traumatic bulbar urethral rupture using temporary urethral stent after primary realignment; retrospective comparison between thermo-expandable urethral stent and self-expandable polymer-coated urethral stent. J Clin Med. 2020;9(5): E1274. Published 2020 Apr 28.

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

American Urological Association. Clinically Localized Prostate Cancer: AUA/ASTRO Guideline 2022. Available at: https://www.auanet.org/guidelines/guidelines/clinically-localized-prostate-cancer-aua/astro-guideline-2022. Accessed February 10, 2023.

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.

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.

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.

Chao M, Ho H, Chan Y, et al. Prospective analysis of hydrogel spacer for patients with prostate cancer undergoing radiotherapy. BJU Int. 2018 Sep;122(3):427-433.

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.

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 July 2021.

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.

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.

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. Health Technology Assessment. Comparative Effectiveness Review of Prostatic Artery Embolization (PAE) for Treatment of Benign Prostatic Hypertrophy (BPH). February 2019; amended August 2019. Updated January 2022.

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 November 2022.

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.

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.

Kimata R, Nemoto K, Tomita Y, et al. Efficacy of a thermo expandable metallic prostate stent (Memokath) in elderly patients with urethral obstruction requiring long-term management with urethral Foley catheters. Geriatr Gerontol. 2015; 15(5):553-558.

Lerner LB, McVary, KT, Barry MJ et al: Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia: AUA Guideline part II, surgical evaluation and treatment . J Urol 2021; 206: 818.

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.

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.

Memokath™. Available at: https://pnnmedical.com/memokath/. Accessed May 10, 2022.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Prostate Cancer, v1.2023. September 16, 2022.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Bladder Cancer, v2.2022. May 20, 2022.

National Institute for Health and Care Excellence (NICE). Medical technologies guidance [MTG35]. Memokath-051 stent for ureteric obstruction. February 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. June 2020.

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.

Paetkau O, Gagne IM, Pai HH, et al. Maximizing rectal dose sparing with hydrogel: A retrospective planning study. J Appl Clin Med Phys. 2019 Mar 19.

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.

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.

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.

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.

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.

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.

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.

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.

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
07/01/2023	**Coverage Rationale** ● Added language to indicate: ○ Radical prostatectomy is proven and medically necessary in conjunction with a radical cystectomy for bladder cancer ○ Ablation of malignant prostate tissue by magnetic field induction is unproven and not medically necessary ● Replaced language indicating "*surgical* prostatectomy is proven and medically necessary in certain circumstances" with "*radical* prostatectomy is proven and medically necessary in certain circumstances **Applicable Codes** ● Added CPT codes 0738T and 0739T ● Added notation to indicate CPT codes 0738T and 0739T are not managed for medical necessity review for the State of Indiana at this time; refer to the most current *Prior Authorization and Notification List* for the UnitedHealthcare Community Plan of Indiana **Supporting Information** ● Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information ● Archived previous policy version CS334IN.03

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 may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. 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.