

**MEDICAL POLICY**

<b>POLICY TITLE</b>	<b>TREATMENTS OF THE PROSTATE</b>
<b>POLICY NUMBER</b>	<b>MP 4.043</b>

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**I. POLICY**

Use of any focal therapy modality as a treatment for the prostate is considered investigational.

There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Radiofrequency water vapor (steam) thermal therapy may be considered **medically necessary** when the following criteria is met:

- The individual is  $\geq 50$  has a diagnosis of benign prostate hypertrophy **AND**
- A prostate volume  $\geq 30\text{cm}^3$  and  $\leq 80\text{cm}^3$

Radiofrequency water vapor (steam) thermal therapy is consider **investigational** for prostate cancer. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

The prostatic urethral lift procedure (UroLift) is considered **medically necessary** when the following criteria is met:

- The individual has a diagnosis of lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH) (e.g., increased urinary frequency, urgency, incontinence, or straining; nocturia; decreased and intermittent force of the stream; hematuria; and the sensation of incomplete bladder emptying) that interfere with activities of daily living; **and**
- The individual has a peak urine flow rate (Qmax) less than 15 cc/sec on a voided volume that is greater than 125 cc; **and**
- The individual has failed a trial of satisfactory voiding with medication (alpha blocker and/or alpha-reductase inhibitor) or intolerance to medication (alpha blocker and/or 5-alpha-reductase inhibitor); **and**
- When prostate size is no greater than 80 grams; **and**
- There is no median lobe enlargement present; **and**
- The patient has normal renal function **and**

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- The patient has no known allergy to nickel; **or**
- In addition to the above criteria, if the individual has a diagnosis or history of prostate cancer and meets either of the following criteria:
  - The individual is not a candidate for surgical resection of the prostate but will be treated by radiation therapy and has symptoms that are so severe that immediate relief is required; **or**
  - The individual is clinically in remission as evidenced by a PSA < 1.0 ng/mL.

The prostatic urethral lift procedure is considered **investigational** for all other indications. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

*Cross-reference:*

**MP-5.053** Magnetic Resonance–Guided Focused Ultrasound

## II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital BlueCross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO - Refer to FEP Benefit Brochure for information on Treatments of the Prostate:

<https://www.fepblue.org/benefit-plans/benefit-plans-brochures-and-forms>

Note\* - The Federal Employee Program (FEP) Service Benefit Plan does not have a medical policy related to these services.

## III. DESCRIPTION/BACKGROUND

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Prostate cancer is the second most common cancer diagnosis men receive in the United States, and the behavior of localized prostate cancer can prove difficult to predict on a case-by-case basis. Most men with the cancer undergo whole-gland treatments, which can often lead to substantial adverse events. To reduce tumor burden and minimize morbidity associated with radical treatment, investigators have developed a therapy known as focal treatment. Focal treatment seeks to ablate either an “index” lesion (defined as the largest cancerous lesion with the highest grade tumor), or, alternatively, to ablate nonindex lesions and other areas where cancer has been known to occur. Addressed in this review are several ablative methods used to remove cancerous lesions in localized prostate cancer (eg, focal laser ablation, high-intensity focused ultrasound, cryoablation, radiofrequency ablation, photodynamic therapy). All methods, except focal laser ablation, use ultrasound guidance to focus on the tumor (focal laser ablation uses magnetic resonance imaging to guide the probe).

For individuals who have primary localized prostate cancer who receive focal therapy using laser ablation, high-intensity focused ultrasound, cryoablation, radiofrequency ablation, or photodynamic therapy, the evidence includes a high-quality systematic review, studies from a

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registry cohort, and numerous observational studies. Relevant outcomes are overall survival, disease-specific survival, symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. The evidence is highly heterogeneous and inconsistently reports clinical outcomes. No prospective, comparative evidence was found for focal ablation techniques vs current standard treatment of localized prostate cancer, including radical prostatectomy, external-beam radiotherapy, or active surveillance. Methods have not been standardized to determine which and how many identified cancerous lesions should be treated for best outcomes. No evidence supports which, if any, of the focal techniques leads to better functional outcomes. Although high disease-specific survival rates have been reported, the short follow-up periods and small sample sizes preclude conclusions on the effect of any of these techniques on overall survival rates. The adverse event rates associated with focal therapies appear to be superior to those associated with radical treatments (eg, radical prostatectomy, external-beam radiotherapy); however, the evidence is limited in its quality, reporting, and scope. The evidence is insufficient to determine the effects of the technology on health outcomes.

Prostate cancer is the second most common cancer diagnosed among men in the United States. According to the National Cancer Institute (NCI), nearly 240,000 new cases were to be diagnosed in the United States in 2013 and would be associated with around 30,000 deaths. Autopsy studies in the pre prostate-specific antigen (PSA) screening era identified incidental cancerous foci in 30% of men 50 years of age, with incidence reaching 75% at age 80 years. However, NCI Surveillance Epidemiology and End Results data have shown age-adjusted cancer-specific mortality rates for men with prostate cancer declined from 40 per 100,000 in 1992 to 22 per 100,000 in 2010. This decline has been attributed to a combination of earlier detection via PSA screening and improved therapies.

**Diagnosis**

From a clinical standpoint, different types of localized prostate cancers may appear similar during initial diagnosis.

However, the cancer often exhibits varying degrees of risk progression that may not be captured by accepted clinical risk categories (eg, D'Amico criteria) or prognostic tools based on clinical findings (eg, PSA titers, Gleason grade, or tumor stage). In studies of conservative management, the risk of localized disease progression based on prostate cancer-specific survival rates at 10 years may range from 15% to 20% to perhaps 27% at 20-year follow-up. Among elderly men ( $\geq 70$  years) with this type of low-risk disease, comorbidities typically supervene as a cause of death; these men will die from the comorbidities with prostate cancer present rather than from the cancer itself. Other very similar appearing low-risk tumors may progress unexpectedly and rapidly, quickly disseminating and becoming incurable.

**Treatments**

The divergent behavior of localized prostate cancers creates uncertainty whether to treat immediately. A patient may choose definitive treatment upfront. Surgery (radical prostatectomy) or external-beam radiotherapy are frequently used to treat patients with localized prostate cancer. Complications most commonly reported with radical prostatectomy or external-beam

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radiotherapy and with the greatest variability are incontinence (0%-73%) and other genitourinary toxicities (irritative and obstructive symptoms); hematuria (typically  $\leq 5\%$ ); gastrointestinal and bowel toxicity, including nausea and loose stools (25%-50%); proctopathy, including rectal pain and bleeding (10%-39%); and erectile dysfunction, including impotence (50%-90%).

American Urological Association guidelines have suggested patients with low- and intermediate-risk disease have the option of entering an “active surveillance” protocol, which takes into account patient age, patient preferences, and health conditions related to urinary, sexual, and bowel function. With this approach, patients forgo immediate therapy but continue regular monitoring until signs or symptoms of disease progression are evident—at which point curative treatment is instituted.

**Focal Treatments for Localized Prostate Cancer**

Given significant uncertainty in predicting the behavior of individual localized prostate cancers, and the substantial adverse events associated with definitive treatments, investigators have sought a therapeutic middle ground. The latter seeks to minimize morbidity associated with radical treatment in those who may not actually require surgery while reducing tumor burden to an extent that reduces the chances for rapid progression to incurability. This approach is termed focal treatment, in that it seeks to remove using any of several ablative methods described next cancerous lesions at high risk of progression, leaving behind uninvolved glandular parenchyma. The overall goal of any focal treatment is to minimize the risk of early tumor progression and preserve erectile, urinary, and rectal functions by reducing damage to the neurovascular bundles, external sphincter, bladder neck, and rectum. Although focal treatments are offered as an alternative middle approach to manage localized prostate cancer, several key issues must be considered in choosing it. They include patient selection, lesion selection, therapy monitoring, and modalities used to ablate lesions.

**Patient Selection**

A proportion of men with localized prostate cancer have been reported to have (or develop) serious misgivings and psychosocial problems in accepting active surveillance, sometimes leading to inappropriately discontinuing it. Thus, appropriate patient selection is imperative for physicians who must decide whether to recommend active surveillance or focal treatment for patients who refuse radical therapy or for whom it is not recommended due to the risk/benefit balance.

**Lesion Selection**

Proper lesion selection is a second key consideration in choosing a focal treatment for localized prostate cancer. Although prostate cancer is a multifocal disease, clinical evidence has shown that between 10% and 40% of men who undergo radical prostatectomy for presumed multifocal disease actually have a unilaterally confined discrete lesion, which, when removed, would “cure” the patient. This view presumably has driven the use of regionally targeted focal treatment variants, such as hemiablation of half the gland containing the tumor, or subtotal prostate ablation via the “hockey stick” method. While these approaches can be curative, the more extensive the treatment, the more likely the functional adverse outcomes would approach those

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of radical treatments. The concept that clinically indolent lesions comprise most of the tumor burden in organ-confined prostate cancer led to development of a lesion-targeted strategy, which is referred to as “focal therapy” in this evidence review. This involves treating only the largest and highest grade cancerous focus (referred to as the “index lesion”), which has been shown in pathologic studies to determine clinical progression of disease.

This concept is supported by molecular genetics evidence that suggests a single index tumor focus is usually responsible for disease progression and metastasis. The index lesion approach leaves in place small foci less than 0.5 cm<sup>3</sup> in volume, with a Gleason score less than 7, that are considered unlikely to progress over a 10- to 20-year period. This also leaves available subsequent definitive therapies as needed should disease progress.

Identification of prostate cancer lesions (disease localization) particularly the index lesion, is critical to the oncologic success of focal therapy; equally important to success is the ability to guide focal ablation energy to the tumor and assess treatment effectiveness. At present, no single modality reliably meets the requirements for all 3 activities (disease localization, focal ablation energy to the tumor, assessment of treatment effectiveness). Systematic transrectal ultrasound-guided biopsy alone has been investigated; however, it has been considered insufficient for patient selection or disease localization for focal therapy. A 5-mm transperineal prostate mapping (TPM) biopsy using a brachytherapy template has been the recommended standard by the European Association of Urology, according to its 2012 guidelines. TPM can provide 3-dimensional coordinates of cancerous lesions, and has 87% to 95% accuracy rates in detecting and ruling out clinically significant cancer of all sizes. However, TPM is resource-intensive, requires general anesthesia, and has been associated with adverse events (including urinary retention [6%], prostatitis [4%], and local events such as perineal hematoma, bruising, and pain [5%]). The risk of complications of general anesthesia and the cost of processing multiple biopsy specimens limits the practicality and widespread applicability of this approach.

Multiparametric magnetic resonance imaging (mpMRI), typically including T1-, T2-, diffusion-weighted imaging, and dynamic contrast-enhanced imaging, has been recognized as a promising modality to risk-stratify prostate cancer and select patients and lesions for focal therapy. Evidence has shown mpMRI can detect high-grade, large prostate cancer foci with performance similar to TPM. For example, for the primary end point definition (lesion,  $\geq 4$  mm; Gleason score,  $\geq 3+4$ ), with TPM as the reference standard, sensitivity, negative predictive value, and negative likelihood ratios with mpMRI were 58% to 73%, 84% to 89%, and 0.3 to 0.5, respectively. Specificity, positive predictive value, and positive likelihood ratios were 71% to 84%, 49% to 63%, and 2.0 to 3.44, respectively. The negative predictive value of mpMRI appears sufficient to rule out clinically significant prostate cancer and may have clinical use in this setting. However, although mpMRI technology has the capability to detect and risk-stratify prostate cancer, several issues constrain its widespread use for these purposes (eg, mpMRI requires highly specialized MRI-compatible equipment; biopsy within the MRI scanner is challenging; interpretation of prostate MRI images requires experienced urologists) and it is still necessary to histologically confirm suspicious lesions using TPM.

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**Therapy Monitoring**

Controversy exists about the proper end points for focal therapy of prostate cancer. The primary end point of focal ablation of clinically significant disease with negative biopsies evaluated at 12 months posttreatment is generally accepted according to a European consensus report. The clinical validity of MRI to analyze the presence of residual or recurrent cancer compared with histologic findings is offered as a secondary end point. However, MRI findings alone are not considered sufficient in follow-up.

Finally, although investigators have indicated PSA levels should be monitored, PSA levels are not considered valid end points because the utility of PSA kinetics in tissue preservation treatments has not been established.

**Modalities Used to Ablate Lesions**

Five ablative methods for which clinical evidence is available are considered herein: focal laser ablation; high-intensity focused ultrasound; cryoablation; radiofrequency ablation; and photodynamic therapy. Each method requires placement of a needle probe into a tumor volume followed by delivery of some type of energy that destroys the tissue in a controlled manner. All methods except focal laser ablation currently rely on ultrasound guidance to the tumor focus of interest; focal laser ablation uses MRI to guide the probe. This evidence review does not cover focal brachytherapy.

*Focal Laser Ablation*

Focal laser ablation refers to the destruction of tissue using a focused beam of electromagnetic radiation emitted from a laser fiber introduced transperineal or transrectal into the cancer focus. Tissue is destroyed through thermal conversion of the focused electromagnetic energy into heat, causing coagulative necrosis. Other terms for focal laser ablation include photothermal therapy, laser interstitial therapy, and laser interstitial photocoagulation.

*High-Intensity Focused Ultrasound*

High-intensity focused ultrasound focuses high-energy ultrasound waves on a single location, which increases the local tissue temperature to over 80°C. This causes a discrete locus of coagulative necrosis of approximately 3×3×10 mm. The surgeon uses a transrectal probe to plan, perform, and monitor treatment in a real-time sequence to ablate the entire gland or small discrete lesions.

*Cryoablation*

Cryoablation induces cell death through direct cellular toxicity from disruption of the cell membrane caused by ice-ball crystals and vascular compromise from thrombosis and ischemia secondary to freezing below -30°C. Using a TPM template, cryoablation is performed by transperineal insertion under transrectal ultrasound guidance of a varying number of cryoprobe needles into the tumor.

*Radiofrequency Ablation*

Radiofrequency ablation uses energy produced by a 50-watt generator at a frequency of 460 kHz. Energy is transmitted to the tumor focus through 15 needle electrodes inserted transperineally

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under ultrasound guidance. Radiofrequency ablation produces an increase in tissue temperature causing coagulative necrosis.

*Photodynamic Therapy*

Photodynamic therapy uses an intravenous photosensitizing agent, which distributes through prostate tissue, followed by light delivered transperineally by inserted needles. The light induces a photochemical reaction that produces reactive oxygen species that are highly toxic and causes functional and structural tissue damage (ie, cell death). A major concern with photodynamic therapy is that real-time monitoring of tissue effects is not possible, and the variable optical properties of prostate tissue complicate assessment of necrosis and treatment progress.

*Transurethral Convective Water Vapor Thermal Ablation*

TUNA using water vapor (ie, Rezūm System) delivers sterile water vapor (steam) transurethrally directly into hyperplastic tissue. Heat is released as the vapor condenses, causing cell death. The major difference between TUNA and Rezūm is how the RF energy is delivered to the prostate. In both cases energy is transferred via a transurethral needle injection. With the former, RF energy is directly delivered to the prostate tissue in a conductive manner. This causes necrosis of the tissue. However, in the Rezūm system the RF energy is used to heat sterile water to vapor and steam which when injected convectively treats the prostate tissue. This latter mechanism is intended to be safer for the patient and yield improved results.

**Benign Prostatic Hyperplasia**

Benign prostatic hyperplasia (BPH) is a common disorder among older men that results from hyperplastic nodules in the periurethral or transitional zone of the prostate. BPH prevalence increases with age and is present in more than 80% of men aged 70 to 79.<sup>1</sup> The clinical manifestations of BPH include increased urinary frequency, urgency, nocturia, hesitancy, and weak stream. The urinary tract symptoms often progress with worsening hypertrophy and may lead to acute urinary retention, incontinence, renal insufficiency, and/or urinary tract infection.

Two scores are widely used to evaluate BPH-related symptoms. The American Urological Association Symptom Index (AUASI) is a self-administered 7-item questionnaire assessing the severity of various urinary symptoms.<sup>2</sup> Total AUASI scores range from 0 to 35, with overall severity categorized as mild ( $\leq 7$ ), moderate (8-19), or severe (20-35). The International Prostate Symptom Score incorporates the questions from the AUASI and a quality of life question or “Bother score.”<sup>3</sup>

**Management of BPH**

Evaluation and management of BPH includes evaluation for other causes of lower urinary tract dysfunction (e.g., prostate cancer). Symptom severity and the degree that symptoms are bothersome determine the therapeutic approach.

**Medical Therapy**

A discussion about medical therapy is generally indicated for patients with moderate-to-severe symptoms (e.g., AUASI score,  $\geq 8$ ), bothersome symptoms, or both. Available medical therapies for BPH-related lower urinary tract dysfunction include  $\alpha$ -adrenergic blockers (e.g., alfuzosin, doxazosin, tamsulosin, terazosin, silodosin),  $5\alpha$ -reductase inhibitors (e.g., finasteride,

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dutasteride), combination  $\alpha$ -adrenergic blockers and  $5\alpha$ -reductase inhibitors, anti-muscarinic agents (e.g., darifenacin, solifenacin, oxybutynin), and phosphodiesterase-5 inhibitors (e.g., tadalafil).

### Surgical and Ablative Therapies

Various surgical or ablative procedures are used to treat BPH. Transurethral resection of the prostate (TURP) is generally considered the reference standard for comparisons of BPH treatments. In the perioperative period, TURP is associated with risks of any operative procedure (e.g., anesthesia risks, blood loss). Although short-term mortality risks are generally low, 1 large prospective study with 10,654 patients reported the following short-term complications: “failure to void (5.8%), surgical revision (5.6%), significant urinary tract infection (3.6%), bleeding requiring transfusions (2.9%), and transurethral resection syndrome (1.4%).” Incidental carcinoma of the prostate was diagnosed by histologic examination in 9.8% of patients. In the longer term, TURP is associated with risk of sexual dysfunction and incontinence.

Several minimally invasive prostate ablation procedures have also been developed, including transurethral microwave thermotherapy, transurethral needle ablation of the prostate, urethromicroablation phototherapy, and photo selective vaporization of the prostate.

### Prostatic Urethral Lift

The prostatic urethral lift procedure involves placement of 1 or more implants in the lateral lobes of the prostate using a transurethral delivery device. The implant device is designed to retract the prostate to allow expansion of the prostatic urethra. The implants are retained in the prostate to maintain an expanded urethral lumen.

One device, the NeoTract UroLift® System (NeoTract, Pleasanton, CA), has clearance for marketing by the U.S. Food and Drug Administration (FDA; see Regulatory Status section). The device has 2 main components: the delivery device and the implant. Each delivery device comes preloaded with 1 UroLift implant.

### Outcome Measures Used in Evaluating BPH Symptoms

A number of health status measures are used to evaluate symptoms relevant to BPH and adverse effects of treatment for BPH, including urinary dysfunction, ejaculatory dysfunction, overall sexual health, and overall quality of life. Some validated scales are shown in Table 1.

**Table 1. Health Status Measure Relevant to Benign Prostatic**

Measure	Outcome Evaluated	Description	Clinically Meaningful Difference (If Known)
Male Sexual Health Questionnaire for Ejaculatory Dysfunction (MSHQ-EJD) <sup>6</sup>	Ejaculatory function	Patient-administered, 4-item scale	
Sexual Health Inventory for Men (SHIM) <sup>7</sup>	Erectile function	Patient-administered, 5-item scale; final score range, 1 (worst symptoms) to 25 (fewest symptoms)	



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American Urological Association Symptom Index (AUASI) <sup>1,8</sup>	Severity of lower urinary tract symptoms	Patient-administered, 7-item scale; final score range, 0 (no symptoms) to 35 (worst symptoms)	Minimum of 3-point change <sup>1,8</sup>
International Prostate Symptom Score (IPSS) <sup>3</sup>	Severity of lower urinary tract symptoms	Patient-administered, 8-item scale	
Benign Prostatic Hyperplasia Impact Index (BPH-II) <sup>9,4</sup>	Effect of urinary symptoms on health domains	Patient-administered, 4-item scale; final score range, 0 (best) to 13 (worst)	Minimum of 0.4-point change <sup>8</sup>
International Prostate Symptom Score (IPSS) <sup>3</sup>	Severity of lower urinary tract symptoms	Patient-administered, 8-item scale	
Benign Prostatic Hyperplasia Impact Index (BPH-II) <sup>9,4</sup>	Effect of urinary symptoms on health domains	Patient-administered, 4-item scale; final score range, 0 (best) to 13 (worst)	Minimum of 0.4-point change <sup>8</sup>
Benign Prostatic Hyperplasia Impact Index (BPH-II) <sup>4,9</sup>	Effect of urinary symptoms on health domains	Patient-administered, 4-item scale; final score range, 0 (best) to 13 (worst)	Minimum of 0.4-point change <sup>8</sup>

**REGULATORY STATUS**

**Focal Laser Ablation**

In 2010, the Visualase® Thermal Therapy System (Medtronic, Minneapolis, MN) and, in 2015, the TRANBERGCLSLaser fiber (Clinical Laserthermia Systems, Sweden) were cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process to necrotize or coagulate soft tissue through interstitial irradiation or thermal therapy under magnetic resonance imaging guidance for multiple indications including urology, at wavelengths from 800 to 1064 nm. FDA product code: LLZ, GEX, FRN.

**High-Intensity Focused Ultrasound**

In 2015, the Sonablate® 450 (SonaCare Medical, Charlotte, NC) was approved by FDA through a de novo request and classified the device as class II under the generic name “high intensity ultrasound system for prostate tissue ablation”. This device was the first of its kind to be approved in the United States. A similar device, Ablatherm® (EDAP TMS, France), was cleared for marketing by FDA through the 510(k) process shortly thereafter.

**Cryoablation**

Some cryoablation devices cleared for marketing by FDA through the 510(k) process for cryoablation of the prostate are: Visual-ICE® (Galil Medical, St. Paul, MN), Ice Rod CX, CryoCare® (Galil Medical), IceSphere (Galil Medical), and Cryocare® Systems (Endocare®; HealthTronics, Austin, TX). FDA product code: GEH.

**Radiofrequency Ablation**

Radiofrequency ablation devices have been cleared for marketing by FDA through the 510(k) process for general use for soft tissue cutting and coagulation and ablation by thermal coagulation. Under this general indication, radiofrequency ablation may be used to ablate tumors. FDA product code: GEI.

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**Photodynamic Therapy**

FDA has granted approval to several photosensitizing drugs and light applicators. Photofrin® (porfimer sodium) (Axcan Pharma) and psoralen are photosensitizer ultraviolet lamps used to treat cancer; they were cleared for marketing by FDA through the 510(k) process. FDA product code: FTC.

**Transurethral Convective Water Vapor Thermal Ablation**

FDA has granted approval to the Rezūm System which delivers sterile water vapor (steam) transurethral directly into hyperplastic tissue through the 510(k) process. FDA product code: KNS.

**Prostatic Urethral Lift**

One implantable transprostatic tissue retractor system has been cleared for marketing by FDA through the 510(k) process. The NeoTract UroLift System (NeoTract, Pleasanton, CA) received clearance in December 2013 (after receiving clearance through FDA’s de novo classification process in March 2013; K130651/DEN130023). In March 2016, FDA determined that the UL500 was substantially equivalent to existing devices (UL400) for the treatment of symptoms of urinary flow obstruction secondary to benign prostatic hyperplasia in men age 50 years and older. FDA product code: PEW.

**IV. RATIONALE**

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**Summary of Evidence: Focal Treatment Overview**

Systematic reviews have reported no published prospective, comparative evidence for focal ablation techniques versus current standard treatment of localized prostate cancer. Evidence consists of case series and noncomparative observational studies. Studies were generally small with short follow-up. Data on clinical outcomes such as progression to metastatic disease were not reported for most studies included in the Valerio review. Perioperative outcomes and other adverse events were also poorly reported.

For individuals who have primary localized prostate cancer who receive focal therapy using laser ablation, high-intensity focused ultrasound, cryoablation, radiofrequency ablation, or photodynamic therapy, the evidence includes a high-quality systematic review, studies from a registry cohort, and numerous observational studies. Relevant outcomes are overall survival, disease-specific survival, symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. The evidence is highly heterogeneous and inconsistently reports clinical outcomes. No prospective, comparative evidence was found for focal ablation techniques vs current standard treatment of localized prostate cancer, including radical prostatectomy, external-beam radiotherapy, or active surveillance. Methods have not been standardized to determine which and how many identified cancerous lesions should be treated for best outcomes. No evidence supports which, if any, of the focal techniques leads to better functional outcomes. Although high disease-specific survival rates have been reported, the short follow-up periods and small sample sizes preclude conclusions on the effect of any of these techniques on overall survival rates. The adverse event rates associated with focal therapies

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appear to be superior to those associated with radical treatments (eg, radical prostatectomy, external-beam radiotherapy); however, the evidence is limited in its quality, reporting, and scope. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Summary of Evidence: Transurethral Convective Water Vapor Thermal Ablation Overview**

The Rezūm System is substantially equivalent to the Prostiva Device (K113380/K142248). It has the same intended use for thermal ablation of BPH tissue. The test and clinical data showed that the technological difference between the Rezūm and its predicate do not raise safety and efficacy issues. The Rezūm II randomized placebo controlled clinical trial data showed that the device is effective in relieving the symptoms of BPH and does not raise new questions of safety. Based on the test data and the same intended use, the Rezūm System is found to be substantially equivalent to its predicate.

**Summary of Evidence: Prostatic Urethral Lift**

For individuals who have lower urinary tract obstruction symptoms (due to BPH) and receive a PUL, the evidence includes systematic reviews, randomized controlled trials, and noncomparative studies. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, and treatment-related morbidity. One randomized controlled trial, the BPH6 study, compared the PUL procedure with transurethral resection of the prostate and reported that the PUL procedure was noninferior for the study’s composite end point, which required concurrent fulfilment of 6 independently validated measures of symptoms, safety, and sexual health. While transurethral resection of the prostate was superior to PUL in managing lower urinary tract symptoms, PUL did provide significant symptom improvement over 2 years. PUL was further superior to transurethral resection of the prostate in preserving sexual function. These findings were corroborated by another randomized controlled trial, entitled the LIFT study, which compared PUL with sham control. Patients underwent washout of BPH medications before enrollment. LIFT reported that patients with the PUL procedure, compared with patients who had sham surgery and no BPH medication, had greater improvements in lower urinary tract symptoms without worsened sexual function at 3 months. After 3 months, patients were given the option to have PUL surgery; 80% of the patients with sham procedures chose that option. Publications from this trial reported that functional improvements were durable over 3-, 4-, and 5-year follow-ups in a subset of patients treated with PUL; there was a high number of exclusions and loss to follow-up in that group. The evidence is sufficient to determine the effects of the technology on health outcomes.

**Practice Guidelines and Position Statements**

**National Comprehensive Cancer Network**

The National Comprehensive Cancer Network guidelines for prostate cancer (v.2.2017) recommend cryosurgery or high-intensity focused ultrasound (HIFU) as options for radiotherapy recurrence for nonmetastatic disease; cryosurgery is not recommended for the initial treatment of localized prostate cancer.

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**National Institute for Health and Care Excellence**

The National Institute for Health and Care Excellence (NICE) issued guidance on the use of cryoablation for localized prostate cancer in 2012. NICE concluded that current evidence on focal therapy using cryoablation for localized prostate cancer raises no major safety concerns. However, evidence on efficacy is limited in quantity, with concern that prostate cancer is commonly multifocal. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.

NICE also issued guidance on the use of focal therapy using high-intensity focused ultrasound (HIFU) for localized prostate cancer in 2012. It concluded that current evidence on HIFU for localized prostate cancer raises no major safety concerns. However, evidence on efficacy is limited in quantity, with concern that prostate cancer is commonly multifocal. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.

In 2014, NICE issued guidance on diagnosis and management of prostate cancer. The recommendations stated that either cryotherapy or HIFU should be offered to men with localized prostate cancer or locally advanced prostate cancer outside of controlled trials comparing their use with established interventions.

In 2014, the National Institute for Health and Care Excellence published interventional procedural guidance on urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia. The guidance stated:

“Current evidence on the efficacy and safety of insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia is adequate to support the use of this procedure.”

In 2015, the Institute published a medical technology guidance on the use of UroLift for treating lower urinary tract symptoms of benign prostatic hyperplasia.<sup>36</sup> The guidance stated: “the UroLift system is effective in relieving symptoms of benign prostatic hyperplasia” and “the UroLift system should be considered as an alternative to current surgical procedures for use in a day-case setting in individuals with lower urinary tract symptoms of benign prostatic hyperplasia who are aged 50 years and older and who have a prostate of less than 100 ml without an obstructing middle lobe.”

**American Urological Association**

The American Urological Association, along with the American Society for Radiation Oncology and the Society for Urologic Oncology, updated their joint guidelines on the management of clinically localized prostate cancer in 2017. The guidelines included the following recommendation on focal treatments:

“Clinicians should inform low-risk prostate cancer patients who are considering focal therapy or high intensity focused ultrasound (HIFU) that these interventions are not standard care options because comparative outcome evidence is lacking. (Expert Opinion)”

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“Clinicians should inform intermediate-risk prostate cancer patients who are considering focal therapy or HIFU that these interventions are not standard care options because comparative outcome evidence is lacking. (Expert Opinion)”

“Cryosurgery, focal therapy and HIFU treatments are not recommended for men with high-risk localized prostate cancer outside of a clinical trial. (Expert Opinion)”

The American Urological Association (AUA) considers transurethral destruction of prostate tissue; by radio-frequency generated water thermotherapy, also known as the Rezum procedure, to be a viable treatment of benign prostatic hyperplasia (BPH). Therefore, this procedure should be covered for reimbursement.

The 2010 (reaffirmed 2014) American Urological Association guidelines on the management of benign prostatic hyperplasia did not address the prostatic urethral lift procedure.

**National Cancer Institute**

The National Cancer Institute (NCI) updated its information on prostate cancer treatments in 2016. NCI indicates cryoablation and HIFU are new treatment options currently being studied in national trials. NCI offered no recommendation for or against these treatments.

**U.S. Preventive Services Task Force Recommendations**

The U.S. Preventive Services Task Force published recommendations for prostate cancer screening. However, there are no recommendations for focal treatment of prostate cancer.

**Medicare National Coverage**

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

**ONGOING AND UNPUBLISHED CLINICAL TRIALS**

Some currently unpublished trials that might influence this policy are listed in Table 1.

**Table 1. Summary of Key Trials**

<b>NCT No.</b>	<b>Trial Name</b>	<b>Planned Enrollment</b>	<b>Completion Date</b>
<b>Ongoing</b>			
<b>NCT02016040</b>	Focal Therapy Using High Intensity Focused Ultrasound (AblathermÂ®) for Localized Prostate Cancer	25	Nov 2017 (ongoing)
<b>NCT02328807</b>	Focal Prostate Radio-Frequency Ablation for the Treatment of Prostate Cancer	30	Jun 2019
<b>Unpublished</b>			
<b>NCT00877682*</b>	Regional Cryoablation for Localized Adenocarcinoma of the Prostate	100	Jan 2018 (completed)
<b>NCT02303054</b>	MRI-US Fusion Biopsy-Guided Focal Radio-Frequency Ablation of the Prostate in Men with Localized Prostate Cancer (FUSAbate Trial)	21	Mar 2016 (completed)

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NCT: national clinical trial.

\*Denotes industry-sponsored or cosponsored trial.

### V. DEFINITIONS

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NONE

### VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

### VII. DISCLAIMER

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*Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital BlueCross' Provider Services or Member Services. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.*

### VIII. CODING INFORMATION

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**Note:** This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

#### Investigational when used to describe Focal Treatments for Prostate Cancer

CPT Codes®							
0582T	55899						

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HCPCS Codes	Description
C2596	Probe, image-guided, robotic, waterjet ablation
C9734	Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (MR) guidance

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<b>HCPCS Codes</b>	<b>Description</b>
C9747	Ablation of prostate, transrectal, high intensity focused ultrasound (HIFU), including imaging guidance

**Covered when Medically Necessary when used for Radiofrequency water vapor (steam) thermal therapy**

<b>CPT Codes®</b>							
53854							

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<b>ICD-10-CM Diagnosis Code</b>	<b>Description</b>
D29.1	Benign Neoplasm of Prostate
N13.8	Other Obstruction and Reflux Uropathy
N32.0	Bladder Neck Obstruction
N40.1	Enlarged Prostate with lower urinary tract symptoms
N40.3	Nodular Prostate with lower urinary tract symptoms
R33.8	Other Retention of Urine
R39.15	Urgency of Urination
R39.16	Straining to Void

**Covered when Medically Necessary for Prostatic Urethral Lift**

<b>CPT Codes®</b>							
52441	52442						

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<b>HCPCS Code</b>	<b>Description</b>
C9739	Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants
C9740	Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants

<b>ICD-10-CM Diagnosis Code</b>	<b>Description</b>
D29.1	Benign Neoplasm of Prostate
N40.1	Enlarged Prostate with lower urinary tract symptoms
N40.3	Nodular Prostate with lower urinary tract symptoms

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**MEDICAL POLICY**

<b>POLICY TITLE</b>	<b>TREATMENTS OF THE PROSTATE</b>
<b>POLICY NUMBER</b>	<b>MP 4.043</b>

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**X. POLICY HISTORY**

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<b>MP 4.043</b>	<b>CAC 11/28/17</b> New policy, adopted BCBSA. Use of any focal therapy modality to treat patients with localized prostate cancer is investigational. FEP variation added. Coding added.
	<b>5/25/18 Minor review.</b> New criteria added for radiofrequency water vapor (steam) thermal therapy to be medically necessary for benign prostate hypertrophy. UroLift policy criteria added to make a further encompassing prostate policy. Title changed to Treatments of the Prostate. Coding updated. Added new code 53854 effective 1/1/19. Noted C9748 will be effective through 12/31/18.

**MEDICAL POLICY**

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	<b>4/3/19 Minor review.</b> Criteria change made to UroLift, other policy statements unchanged. References updated. Removed expired coding, C9748.
	<b>1/1/20 Admin update.</b> Added new code 0582T & C2596.
	<b>4/3/20 Consensus review.</b> Policy Statement unchanged. ICD codes: N13.8; R33.8; R39.15; R39.16 added and updated. References reviewed and updated. Variations updated.

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