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## OVERVIEW

Prostate cancer is the second most common cancer diagnosis men receive in the U.S., and the behavior of localized prostate cancer can prove difficult to predict on a case-by-case basis. Most men with prostate 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 non index lesions and other areas where cancer has been known to occur. There are several ablative methods used to remove cancerous lesions in localized prostate cancer (eg, focal laser ablation, high-intensity focused ultrasound [HIFU], cryoablation, radiofrequency ablation [RFA], 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).

## MEDICAL CRITERIA

Not applicable.

## PRIOR AUTHORIZATION

Not applicable.

## POLICY STATEMENT

### Medicare Advantage Plans

Use of any focal therapy modality to treat patients with localized prostate cancer is not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

### Commercial Products

Use of any focal therapy modality to treat patients with localized prostate cancer is not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

## COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

## BACKGROUND

### Localized Prostate Cancer and Current Management

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 are expected to be diagnosed in the United States in 2013 and are associated with around 30,000 deaths. Autopsy studies in the pre-prostate-specific antigen (PSA) screening era have 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 show age-adjusted cancer-specific mortality rates for men with prostate cancer have 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.

Localized prostate cancers may appear very similar clinically at diagnosis. However, they often exhibit diverse risk of progression that may not be captured by accepted clinical risk categories (e.g., D'Amico criteria) or prognostic tools that are based on clinical findings, including PSA titers, Gleason grade, or tumor stage.

In studies of conservative management, the risk of localized disease regression 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 (70 years) with this type of low-risk disease, comorbidities typically supervene as a cause of death; these men will die with prostate cancer present, rather than from the cancer. Other very similar-appearing low-risk tumors may progress unexpectedly rapidly, quickly disseminating and becoming incurable.

The divergent behavior of localized prostate cancers creates uncertainty whether to treat immediately. A patient may choose definitive treatment upfront. Surgery (radical prostatectomy), or EBRT are most commonly used to treat patients with localized prostate cancer. Complications most commonly reported with radical prostatectomy or EBRT and with the greatest variability are incontinence (0%-73%) and other genitourinary toxicities (irritative and obstructive symptoms); hematuria (typically <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 (AUA) guidelines suggest patients with low- and intermediate-risk disease have the option of entering an "active surveillance" protocol, that takes into account patient age, patient preferences, and health conditions related to urinary, sexual, and bowel function. With this approach the patient will forgo immediate therapy but continue regular monitoring until signs or symptoms of disease progression are evident, at which point curative treatment is instituted.

### **Focal Treatment of Localized Prostate Cancer**

Given the uncertainty in predicting behavior of individual localized prostate cancers, and the substantial adverse effects associated with definitive treatments in patients with such disease, investigators have sought a middle ground that seeks to minimize morbidity associated with radical treatment in those who may not actually require it 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 in the Background of this Policy) cancerous lesions at high risk of progression, leaving behind uninvolved glandular parenchyma. The overall goal of focal treatment is to minimize the risk of early tumor progression and preserve erectile, urinary, and rectal functions reducing damage to the neurovascular bundles, external sphincter, bladder neck, and rectum. Although focal treatment is offered as an alternative middle approach to management of localized prostate cancer, several key issues must be considered in choosing it. These include patient selection, lesion selection, therapy monitoring, and the modality used to ablate lesions.

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 individual patients who refuse radical therapy or for whom it is not recommended due to the adverse balance of certain harms with unclear long-term benefit.

Proper lesion selection is a second key consideration in choosing to undertake focal treatment of localized prostate cancer. Although prostate cancer has always been regarded as a multifocal disease, clinical evidence shows 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 patients. This view presumably drove the use of region-targeted focal treatment variants, such as hemi-ablation of the half of the gland containing tumor, or subtotal prostate ablation via the "hockey stick" method. While these approaches could be curative, the more extensive the treatment, the more likely the functional adverse outcomes would approach those of radical treatments.

The concept that clinically indolent lesions usually comprise most of the tumor burden in a patient with organ-confined prostate cancer led to development of the lesion-targeted strategy, which is referred to as “focal therapy” in this Policy. This involves treating only the largest and highest-grade tumor (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 in volume, with 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 oncologic success of focal therapy. The ability to guide focal ablation energy to the tumor and assess treatment effectiveness, is additionally important to treatment success. At present, no single modality meets the requirements for all 3 activities. Systematic transrectal ultrasound (TRUS)-guided biopsy alone has been investigated but is considered insufficient for the purpose of patient selection and disease localization for focal therapy. A 5mm transperineal prostate mapping (TPM) biopsy using a brachytherapy template is the current recommended standard by the European Association of Urology in their 2012 guidelines. TPM can provide 3-dimensional coordinates of cancerous lesions and has about 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, or pain (5%). The risk of complications of general anesthesia and the cost of processing multiple biopsy specimens have been considered to limit the practicality and widespread applicability of this approach.

Multiparametric magnetic resonance imaging (mp-MRI), 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 is available to show mp-MRI can detect high grade, large prostate cancer foci with performance similar to TPM. In this cohort study, for the primary end point definition (lesion, 4 mm; and Gleason score, 3+4), with TPM as the reference standard, sensitivity, negative predictive value, and negative likelihood ratios with mp-MRI 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 mp-MRI appears sufficient to rule out clinically significant prostate cancer and may have clinical use in this setting. However, although mp-MRI technology has capability to detect and risk-stratify prostate cancer, several issues constrain its widespread use for these purposes. Thus, it is still necessary to histologically confirm suspicious lesions using TPM; mp-MRI requires highly specialized MRI-compatible equipment; biopsy within the MRI scanner is challenging; and, interpretation of prostate MRI images requires experienced urologists.

Some controversy exists as to 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 after treatment is generally agreed on 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 indicate PSA levels should be monitored, they are not considered as valid end points because the utility of PSA kinetics in tissue preservation treatments has not been established.

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 non-comparative 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 1 high-quality systematic review, studies from 1 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 versus current standard treatment of localized prostate cancer, including radical prostatectomy, external-beam radiotherapy (EBRT), 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 effect rates associated with focal therapies appear to be superior to those associated with radical treatments (eg, radical prostatectomy, EBRT), however, evidence is limited in its quality, reporting, and scope. The evidence is insufficient to determine the effects of the technology on health outcomes.

### **CODING**

The following code(s) are not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

- 0655T** Transperineal focal laser ablation of malignant prostate tissue, including transrectal imaging guidance, with MR-fused images or other enhanced ultrasound imaging
- 55880** Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound (HIFU), including ultrasound guidance

CPT codes have not been assigned to all of the services or therapies addressed in this policy. Therefore, the following Unlisted procedure code(s) should be used:

- 55899** Unlisted procedure, male genital system

### **RELATED POLICIES**

New Technology and Miscellaneous Services  
Unlisted Procedures

### **PUBLISHED**

Provider Update, June 2022  
Provider Update, June 2021  
Provider Update, January 2021  
Provider Update, December 2019

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