Introduction

There are several ways to treat prostate cancer, depending on how large the cancer is and whether it’s spread. Some treatment choices are surgery, several different types of radiation, or watchful waiting. A new type of treatment has been proposed. This treatment, known as focal therapy, aims at destroying specific areas of cancer without taking out the prostate gland. There are different ways of trying to treat the tumor while it’s still inside the gland. These are laser, ultrasound, extreme cold, radiofrequency, and cell-killing drugs that are activated by a special type of light. All forms of focal therapy for prostate cancer are unproven (investigational). Larger and longer studies are needed to see if focal treatments are as good as or better than proven methods of treating prostate cancer.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
Use of any focal therapy modality to treat patients with localized prostate cancer is investigational.

### Coding

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<tr>
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<td>Unlisted procedure, urinary system</td>
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<tr>
<td>55899</td>
<td>Unlisted procedure, male genital system</td>
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### Related Information

N/A

### Evidence Review

**Description**

Prostate cancer is the second most common cancer diagnosed in men in the United States, and the behavior of localized prostate cancer can be 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 side events. To reduce tumor burden and minimize morbidity associated with radical treatments, investigators have developed a therapy known as focal treatment. This policy addresses several ablative methods used to remove cancerous lesions in localized prostate cancer (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).

Background

Prostate Cancer

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 about 30% of men 50 years of age or older. However, NCI Surveillance Epidemiology and End Results data have shown 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.

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 of 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). Among elderly men (≥70 years) with one type of low-risk disease, comorbidities typically supervene as a cause of death; these men will die from the comorbidities with prostate cancer being 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 (EBRT) are frequently used to treat patients with localized prostate cancer. Complications most commonly reported with radical prostatectomy or EBRT and with the greatest variability are incontinence and other genitourinary toxicities (irritative and obstructive symptoms); hematuria; gastrointestinal and bowel toxicity,
including nausea and loose stools; proctopathy, including rectal pain and bleeding; and erectile dysfunction, including impotence.\textsuperscript{15}

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.\textsuperscript{16} 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.\textsuperscript{17,18}

\textbf{Focal Treatment of Localized Prostate Cancer}

Given the significant uncertainty in predicting the behavior of individual localized prostate cancers and the substantial adverse effects associated with definitive treatments, investigators have sought a therapeutic middle ground. This approach seeks to minimize the morbidity associated with radical treatment in those who may not actually require it while also reducing tumor burden to an extent that lowers the risk for the tumor rapidly progressing to being incurable. This approach is termed focal treatment, in that it seeks to remove 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 by reducing damage to the neurovascular bundles, external sphincter, bladder neck, and rectum.\textsuperscript{19-23} Although focal treatments are offered as an alternative middle approach to management of localized prostate cancer, several key issues must be considered in choosing it. They include patient selection, lesion selection, therapy monitoring, and the modality used to ablate lesions.

\textbf{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.\textsuperscript{24} 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.\textsuperscript{25}
Lesion Selection

Proper lesion selection is a second key consideration in choosing focal treatment for localized prostate cancer. Although prostate cancer is often a multifocal disease, clinical evidence has shown that it is not uncommon for 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 tumor, or subtotal prostate ablation via the “hockey stick” method. While these approaches can be curative, the more extensive the treatment, the more likely that the functional adverse outcomes would approach those 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 policy. 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 cm³ 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 the disease progress.

Identification of prostate cancer lesions (disease localization), particularly the index lesion, is critical to obtaining oncologic success when using 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 (TRUS)‒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 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, 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, ≥4 mm; Gleason score, ≥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. For example, mpMRI requires highly specialized MRI-compatible equipment, biopsy within the MRI scanner is challenging, interpretation of prostate MRI images requires experienced uroradiologists, and it is still necessary to histologically confirm suspicious lesions using TPM.

**Therapy Monitoring**

Controversy exists about the proper end points for focal therapy of prostate cancer. A European consensus report suggests that the primary end point should be focal ablation of clinically significant disease with negative biopsies at 12 months posttreatment. The clinical validity of using MRI to analyze the presence of residual or recurrent cancer compared with histologic findings is suggested 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, 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 in this policy: focal laser ablation (FLA); high-intensity focused ultrasound; cryoablation; radiofrequency ablation (RFA); and photodynamic therapy (PDT). 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 FLA currently rely on ultrasound guidance to the tumor focus of interest; FLA uses MRI to guide the probe.
**Focal Laser Ablation**

FLA refers to the destruction of tissue using a focused beam of electromagnetic radiation emitted from a laser fiber introduced transperineally or transrectally into the cancer focus. Tissue is destroyed through thermal conversion of the focused electromagnetic energy into heat, causing coagulative necrosis. Other terms for FLA include photothermal therapy, laser interstitial therapy, and laser interstitial photocoagulation.\(^{51}\)

**High-Intensity Focused Ultrasound**

High-intensity focused ultrasound works by focusing 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 3x3x10 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, transrectal ultrasound is used to guide the transperineal insertion of a varying number of cryoprobe needles into the tumor.

**Radiofrequency Ablation**

RFA uses energy produced by a 50-watt generator with a frequency of 460 kHz. Energy is transmitted to the tumor focus through 15 needle electrodes inserted transperineally under ultrasound guidance. RFA increases tissue temperature causing coagulative necrosis.

**Photodynamic Therapy**

PDT uses an oral or intravenous photosensitizing agent that accumulates within the prostate. Special needles are inserted transperineally into the prostate, and light of a certain wavelength is delivered through the needles into the prostate. The light induces a photochemical reaction that
is highly toxic and causes functional and structural damage (ie, cell death). A major concern with PDT 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.

Summary of Evidence

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 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 event 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.

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

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<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
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<td>Focal Therapy Using High Intensity Focused Ultrasound</td>
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<td>NCT023228807</td>
<td>Focal Prostate Radio-Frequency Ablation for the Treatment of Prostate Cancer</td>
<td>30</td>
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<tr>
<td>NCT00877682</td>
<td>Regional Cryoablation for Localized Adenocarcinoma of the Prostate</td>
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**Unpublished**

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<td>A European Randomized Phase 3 Study to Assess the Efficacy and Safety of TOOKAD® Soluble for Localized Prostate Cancer Compared to Active Surveillance</td>
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<td>NCT02303054</td>
<td>MRI-US Fusion Biopsy-Guided Focal Radio-Frequency Ablation of the Prostate in Men with Localized Prostate Cancer (FUSAblate Trial)</td>
<td>21</td>
<td>Mar 2016 (completed)</td>
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NCT: national clinical trial.

**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.63

**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 2012.49 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.

NICE also issued guidance on the use of focal therapy using high-intensity focused ultrasound (HIFU) for localized prostate cancer in 2012.50 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.

In 2014, NICE issued guidance on diagnosis and management of prostate cancer. The recommendations stated that neither cryotherapy nor 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.64

**American Urological Association et al**

The American Urological Association (AUA) 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 2017.16 The guidelines include 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)

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)

**National Cancer Institute**

The National Cancer Institute (NCI) updated its information on prostate cancer treatments in 2016.65 NCI indicated that cryoablation and HIFU were new treatment options currently being studied in national trials. NCI offers 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.

Regulatory Status

Focal Laser Ablation

In 2010, the Visualase® Thermal Therapy System (Medtronic, Minneapolis, MN) and, in 2015, the TRANBERG® Laser 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 MRI guidance for multiple indications including urology, at wavelengths 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 the FDA through the 510(k) process shortly thereafter.

Cryoablation

Some cryotherapy devices cleared for marketing by the 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

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

FDA product code: GEI.

Photodynamic Therapy

The 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 from marketing by the FDA through the 510(k) process.

FDA product code: FTC.

References


20. Nguyen CT, Jones JS. Focal therapy in the management of localized prostate cancer. BJU Int. May 2011;107(9):1362-1368. PMID 21223478


44. Crawford ED, Rove KO, Barqawi AB, et al. Clinical-pathologic correlation between transperineal mapping biopsies of the prostate and three-dimensional reconstruction of prostatectomy specimens. Prostate. May 2013;73(7):778-787. PMID 23169245


Date | Comments
--- | ---
07/14/15 | New Policy. Policy created with literature review through March 3, 2015. Use of any focal therapy modality is considered investigational for treatment of localized prostate cancer.
11/01/16 | Annual Review, approved October 11, 2016. Policy updated with literature review through July 26, 2016; references 55-57 and 59-63 were added. Policy statement unchanged.
08/01/17 | Interim review, approved July 11, 2017. Policy moved into new format. No changes to policy statement.

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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room S9FF, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

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