

## Corporate Medical Policy

### Focal Treatments for Prostate Cancer

**File Name:** focal\_treatments\_for\_prostate\_cancer  
**Origination:** 6/2017  
**Last Review:** 11/2024

#### Description of Procedure or Service

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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 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 nonindex lesions and other areas where cancer has been known to occur. Addressed in this policy are several ablative methods used to remove cancerous lesions in localized prostate cancer (e.g., focal laser ablation, high-intensity focused ultrasound [HIFU], cryoablation, radiofrequency ablation [RFA], photodynamic therapy, irreversible electroporation).

#### Modalities Used to Ablate Lesions

The following ablative methods for which clinical evidence is available are considered in this policy. 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.

#### Focal Laser Ablation (FLA)

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.

#### High-Intensity Focused Ultrasound

High-intensity focused ultrasound focuses high-energy ultrasound waves on a single location, which increase 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. Cryoablation is performed by transperineal insertion under transrectal ultrasound (TRUS) guidance of a varying number of cryoprobe needles into the tumor, using a transperineal prostate mapping (TPM) template.

#### Radiofrequency Ablation (RFA)

# Focal Treatments for Prostate Cancer

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

## **Photodynamic Therapy (PDT)**

PDT 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 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.

## **Irreversible electroporation**

Electroporation generates high-frequency electric pulses between two or more electrodes which produces an electric current that damages the cell membrane and allows molecules to pass into the cell passively. Electroporation can be temporary (reversible electroporation) or permanent (irreversible electroporation or IRE). In IRE the cell membrane is permanently damaged causing cell death due to the inability to maintain homeostasis. IRE achieves its action with no thermal effect. IRE appears to preserve vessels, nerves and the extracellular matrix.

## **REGULATORY STATUS**

### **Focal Laser Ablation**

In 2010, the Visualase® Thermal Therapy System (Medtronic) and, in 2015, the TRANBERG®CLS Laser fiber (Clinical Laserthermia Systems) 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. In 2020, the FDA cleared the Avenda Health focal laser ablation system and in 2021, the FDA granted a breakthrough device designation for the Avenda artificial intelligence (AI)-enabled focal therapy system for the treatment of localized prostate cancer. In 2023, FDA cleared the Elesta Laser Thermal Therapy Kit to direct laser energy to soft tissue, to necrotize or coagulate soft tissue through interstitial irradiation in medicine and surgery including urology, at a wavelength of 1064nm.

### **High-Intensity Focused Ultrasound**

In 2015, the Sonablate® 450 (SonaCare Medical) 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. In November 2015, Ablatherm®-HIFU (EDAP TMS) was cleared for marketing by the FDA through the 510(k) process. In June 2018, EDAP received 510(k) clearance for its Focal-One® HIFU device designed for prostate tissue ablation procedures. This device fuses magnetic resonance and 3D biopsy data with real-time ultrasound imaging, allowing urologists to view detailed images of the prostate on a large monitor and direct high-intensity ultrasound waves to ablate the targeted area.

### **Cryoablation**

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

### **Radiofrequency Ablation**

Radiofrequency ablation (RFA) 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, RFA may be used to ablate tumors.

# Focal Treatments for Prostate Cancer

## **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, that were cleared for marketing by FDA through the 510(k) process.

In 2020, an FDA advisory committee voted against recommending approval of padeliporfin di-potassium (Tookad®; Steba Biotech), a minimally invasive photodynamic therapy for localized prostate cancer, citing concerns that men with very low-risk disease would potentially choose this therapy instead of active surveillance, despite the unproven long-term benefits and harms of treatment.

## **Irreversible electroporation**

The NanoKnife System was cleared through the 510(k) process (K102329) in 2011 for the surgical ablation of soft tissue. NanoKnife has not received clearance for the treatment of any specific disease.

***\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

## **Policy**

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**Use of any focal therapy modality to treat individuals with localized prostate cancer is investigational. BCBSNC does not provide coverage for investigational services or procedures.**

## **Benefits Application**

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This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

## **When Focal Treatments for Prostate Cancer are covered**

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Not applicable.

## **When Focal Treatments for Prostate Cancer are not covered**

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Use of any focal therapy modality to treat individuals with localized prostate cancer is investigational.

## **Policy Guidelines**

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For individuals who have primary localized prostate cancer who receive focal therapy using laser ablation, high-intensity focused ultrasound, cryoablation, radiofrequency ablation, photodynamic therapy, or irreversible electroporation the evidence includes systematic reviews, studies from one 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 the majority of 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

# Focal Treatments for Prostate Cancer

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 that the technology results in an improvement in the net health outcome.

## **Billing/Coding/Physician Documentation Information**

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbssc.com](http://www.bcbssc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable service codes: 0582T, 0655T, 55880, 55899*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

## **Scientific Background and Reference Sources**

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BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.61, 9/8/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.61, 9/14/2017

Specialty Matched Consultant Advisory Panel 11/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.61, 9/13/2018

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U.S. Preventive Services Task Force. Final Recommendation Statement: Prostate Cancer: Screening. 2018;

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# Focal Treatments for Prostate Cancer

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National Institute for Health and Care Excellence (NICE). Focal Therapy Using High-Intensity Focused Ultrasound for Localized Prostate Cancer [IPG756]. 2023; <https://www.nice.org.uk/guidance/ipg756>.

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Specialty Matched Consultant Advisory Panel 11/2023

Medical Director Review 11/2023

Scheltema MJ, van den Bos W, de Bruin DM, et al. Focal vs extended ablation in localized prostate cancer with irreversible electroporation; a multi-center randomized controlled trial. *BMC Cancer*. May 05 2016; 16: 299. PMID 27150293

George AK, Miocinovic R, Patel AR, et al. A Description and Safety Overview of Irreversible Electroporation for Prostate Tissue Ablation in Intermediate-Risk Prostate Cancer Patients: Preliminary Results from the PRESERVE Trial. *Cancers (Basel)*. Jun 08 2024; 16(12). PMID 38927884

Specialty Matched Consultant Advisory Panel 11/2024

Medical Director Review 11/2024

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## Policy Implementation/Update Information

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# Focal Treatments for Prostate Cancer

- 6/30/17 New policy developed. Focal treatments for prostate cancer are considered investigational. **Notification given 6/30/2017 for effective date 9/29/2017.** (sk)
- 10/27/17 Reference added. Minor revisions to Description of Procedure. (sk)
- 12/15/17 Specialty Matched Consultant Advisory Panel review 11/29/2017. (sk)
- 12/29/17 Code C9748 added to Billing/Coding section for effective date 1/1/2018. (sk)
- 12/14/18 Reference added. Specialty Matched Consultant Advisory Panel review 11/28/2018. (sk)
- 12/10/19 Reference added. Specialty Matched Consultant Advisory Panel review 11/20/2019. (sk)
- 1/14/20 CPT code 0582T added to Billing/Coding section. (sk)
- 12/31/20 Reference added. Deleted codes C9747 and C9748 removed from Billing/Coding section. Specialty Matched Consultant Advisory Panel review 11/18/2020. (sk)
- 5/18/21 Added new code 55880 to the Billing/Coding section. (sk)
- 7/1/21 Added new code 0655T to the Billing/Coding section. (sk)
- 12/14/21 Reference added. Regulatory Status updated. Specialty Matched Consultant Advisory Panel review 11/17/2021. (sk)
- 5/30/23 Policy review. Reference added. Specialty Matched Consultant Advisory Panel review 11/16/2022. (sk)
- 12/29/23 References added. Specialty Matched Consultant Advisory Panel review 11/2023. Medical Director review 11/2023. (rp)
- 12/17/24 References added. Description and Policy Guidelines updated to include irreversible electroporation. No changes to the coverage criteria. Specialty Matched Consultant Advisory Panel review 11/2024. Medical Director review 11/2024. (rp)

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.