



MEDICAL COVERAGE GUIDELINES  
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 06/16/15  
LAST REVIEW DATE: 10/16/18  
LAST CRITERIA REVISION DATE: 10/16/18  
ARCHIVE DATE:

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## FOCAL TREATMENTS FOR PROSTATE CANCER

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Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

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The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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## **FOCAL TREATMENTS FOR PROSTATE CANCER (cont.)**

### **Description:**

Focal treatment refers to using ablative techniques to target only those areas of the prostate that harbor a tumor, rather than the entire gland. When using focal therapy, only the cancer in the gland is ablated leaving much of the gland untreated and minimizing the side effects from treatment. Focal laser methods addressed in this guideline include focal laser ablation (FLA), high intensity focused ultrasound (HIFU), cryoablation, radiofrequency thermal ablation (RFA) and photodynamic therapy (PDT). All of these methods currently rely on ultrasound guidance to the tumor focus of interest.

### **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. It is performed by transperineal insertion under TRUS guidance of a varying number of cryoprobe needles into the tumor.

### **Focal Laser Ablation (FLA):**

Focal Laser Ablation refers to the destruction of tissue using a focused beam of electromagnetic radiation emitted from a laser. It is accomplished through transperineal or transrectal introduction of a laser fiber into the cancer focus, with emission of energy. Tissue is destroyed by FLA 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 (HIFU):**

High-intensity focused ultrasound (US) works by focusing high-energy US waves on a single location, which increases the local tissue temperature. This causes a coagulative necrosis. A transrectal probe is used to monitor treatment in a real-time sequence to ablate the entire gland, or small discrete lesions.

### **Photodynamic Therapy (PDT):**

PDT involves the use of an intravenous photosensitizing agent that distributes to prostate tissue, followed by delivery of light via transperineally inserted needles. The light induces a photochemical reaction that causes production of reactive oxygen species that are highly toxic and reactive with tissue causing functional and structural damage, hence 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.

### **Radiofrequency Thermal Ablation (RFA):**

Radiofrequency thermal ablation uses energy produced by a 50-watt generator with a frequency of 460 kHz. The energy is transmitted to the tumor focus through 15 needle electrode inserted transperineally under US guidance into the tissue. It produces an increase in tissue temperature causing coagulative necrosis.



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## FOCAL TREATMENTS FOR PROSTATE CANCER (cont.)

### Criteria:

For whole gland cryoablation of prostate cancer, see BCBSAZ Medical Coverage Guideline #O759, "Whole Gland Cryoablation of Prostate Cancer".

**COVERAGE FOR HIGH-INTENSITY FOCUSED ULTRASOUND (HIFU) IS DEPENDENT UPON BENEFIT PLAN LANGUAGE. REFER TO MEMBER'S SPECIFIC BENEFIT PLAN BOOKLET TO VERIFY BENEFITS.**

- Focal treatments for prostate cancer using any of the focal therapy modalities to treat individuals with localized prostate cancer is considered ***experimental or investigational*** based upon:
1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives and
  4. Insufficient evidence to support improvement outside the investigational setting.

These modalities include, *but are not limited to*:

- Cryoablation
- Focal laser ablation (FLA)
- High-intensity focused ultrasound (HIFU)
- Photodynamic therapy (PDT)
- Radiofrequency thermal ablation (radiofrequency ablation, RFA)

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### Resources:

Literature reviewed 10/16/18. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

1. 8.01.61 BCBS Association Medical Policy Reference Manual. Focal Treatments for Prostate Cancer. Re-issue date 09/13/2018, issue date 09/10/2015.



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## FOCAL TREATMENTS FOR PROSTATE CANCER (cont.)

### Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, [crc@azblue.com](mailto:crc@azblue.com). You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

### Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nilinígíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idíílkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idíílkidgo beehaz'áanii hólg díí t'áa hazaadk'ehjí háká a'doowołgo bee haz'ą doo baqah ilínígóó. Ata' halne'ígíí kojí' bich'í' hodíilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.

