



Louisiana

Focal Treatments for Prostate Cancer

Policy # 00484

Original Effective Date: 12/16/2015

Current Effective Date: 12/20/2017

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Whole Gland Cryoablation of Prostate Cancer is addressed separately in medical policy 00022.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers use of any focal therapy modality to treat patients with localized prostate cancer to be **investigational**.*

Background/Overview

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 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 (≥ 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 radiotherapy and with the greatest

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Focal Treatments for Prostate Cancer

Policy # 00484

Original Effective Date: 12/16/2015

Current Effective Date: 12/20/2017

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 of radical treatments.

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Focal Treatments for Prostate Cancer

Policy # 00484

Original Effective Date: 12/16/2015

Current Effective Date: 12/20/2017

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 cm³ 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, ≥ 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.

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Focal Treatments for Prostate Cancer

Policy # 00484

Original Effective Date: 12/16/2015

Current Effective Date: 12/20/2017

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.

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

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Focal Treatments for Prostate Cancer

Policy # 00484

Original Effective Date: 12/16/2015

Current Effective Date: 12/20/2017

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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Focal Laser Ablation

In 2010, the Visualase^{®†} Thermal Therapy System (Medtronic, Minneapolis, MN) and, in 2015, the TRANBERG^{CLSt†} Laser fiber (Clinical Laserthermia Systems, Sweden) were cleared for marketing by the U.S. 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.

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.

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Focal Treatments for Prostate Cancer

Policy # 00484

Original Effective Date: 12/16/2015

Current Effective Date: 12/20/2017

Centers for Medicare and Medicaid Services (CMS)

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

Rationale/Source

Assessment of efficacy for therapeutic intervention involves a determination of whether the intervention improves health outcomes. The optimal study design for this purpose is a randomized controlled trial (RCT) that includes clinically relevant measures of health outcomes. Intermediate outcome measures, also known as surrogate outcome measures, may also be adequate if there is an established link between the intermediate outcome and true health outcomes. Nonrandomized comparative studies and uncontrolled studies can sometimes provide useful information on health outcomes, but are prone to biases such as noncomparability of treatment groups, placebo effect, and variable natural history of the condition.

No prospective, comparative studies were identified for any of the ablative technologies. The evidence comprises systematic reviews of noncomparative studies, case series, and other observational studies. This review only includes evidence on primary focal therapy for prostate cancer; it does not consider the recurrent or salvage setting.

FOCAL TREATMENTS OVERVIEW

A high-quality systematic review published by Valerio et al in 2014 compiled the bulk of the evidence available in the literature on the technologies included herein through 2012. This systematic review was performed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. Only studies that reported actual focal therapy procedures were included. Specific categories of data to be collected were prespecified. Study selection criteria were prespecified, with dual review and data extraction, and senior author arbitration as needed. The quality of included studies was assessed using the Oxford Centre for Evidence-based Medicine level of evidence for therapy. This review and its summarized statistics serve as the initial evidence source for this evidence review. Additional prospective studies of a comparative nature are reviewed in subsequent sections below.

Twenty-five series were included that evaluated a number of methods used for focal therapy in the primary setting. The quality of evidence was low to medium, with no study yielding a level of evidence greater than 2b (individual cohort study). Twelve series used high-intensity focused ultrasound (n=226); 6 series (n=1400) used cryoablation (1 study included 1160 treated in the primary setting, 1400 total treated with cryoablation); 3 used focal laser ablation (n=16); 1 used radiofrequency ablation (n=14); and 1 used photodynamic therapy (n=6). In 2 series, focal treatments were mixed or included brachytherapy.

Patients in 12 series included had disease defined as low risk (n=1109 [56%]), intermediate risk (n=704 [36%]), and high risk (n=164 [8%]); risk categories were not available in 13 series. The median age of patients ranged from 56 to 73 years. The prostate-specific antigen (PSA) level of patients ranged from 3.8 to 24 ng/mL. Individual Gleason scores were available in 20 series, with 1503 men having Gleason scores less than 6; 521 with Gleason scores of 7; and 82 had Gleason scores higher than 8. The median follow-up

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Focal Treatments for Prostate Cancer

Policy # 00484

Original Effective Date: 12/16/2015

Current Effective Date: 12/20/2017

for the series ranged from 0 to 10.6 years. The disease was localized as follows: transrectal ultrasound biopsy in 2 series; transrectal ultrasound biopsy with Doppler ultrasound in 2 series; transrectal ultrasound biopsy plus magnetic resonance imaging in 6 series; transperineal template-guided mapping biopsy and multiparametric magnetic resonance imaging in 4 series; preoperative assessment was not reported in 11 studies.

In all studies reporting such data in the Valerio systematic review, all known areas of cancer were treated; in no study was it explicitly stated that the index lesion was ablated and that other lesions were left untreated. Biochemical control based on PSA levels was reported in 5 series using the RTOG-ASTRO Phoenix Consensus Conference criteria. Other definitions used to define biochemical control were American Society for Radiation Oncology (ASTRO; 5 series), Stuttgart (1 series), and Phoenix plus PSA velocity greater than 0.75 ng/mL annually (1 series). Biochemical control rates ranged from 86% at 8-year follow-up (n=318) to 60% at 5-year follow-up (n=56). Because follow-up was too short, progression to metastatic disease was not reported for most studies in the Valerio review; in those reporting follow-up data, metastatic progression rates were very low (0%-0.3%). Although a cancer-specific survival rate of 100% was reported in all series, such rates must be considered in the context of the small numbers of patients in individual studies and the short follow-up (only 3 studies had follow-up >5 years).

Across all studies, median hospital length of stay was 1 day; other perioperative outcomes were poorly reported. Across studies, the most frequent complications associated with treatment of prostate cancer—urinary retention, urinary stricture, and urinary tract infection—occurred in 0% to 17%, 0% to 5%, and 0% to 17%, respectively, of patients. Only 5 studies reported all 3 complications. Validated questionnaires were used in 9 series to report urinary functional outcomes; physician-reported rates were used in 5 studies. According to questionnaires, the pad-free continence rate varied between 95% and 100%, whereas the range of leak-free rates was 80% to 100%. Validated questionnaire data showed erectile functional rates in 54% to 100%, while physician-reported data showed erectile functional rates of 58% to 85%. Other adverse outcomes were poorly reported, particularly quality of life data, with only 3 studies reporting.

In 2015, Wolff et al reported on results of a systematic review of randomized controlled trials of radiotherapy vs other nonpharmacologic treatments, including high-intensity focused ultrasound and cryoablation for treatment of localized prostate cancer. The review followed Centre for Reviews and Dissemination and Cochrane guidelines for conduct and reporting. The selection criteria and outcomes of interest were prespecified. The search included publications up to February 2014. Reviewers found 2 randomized controlled trials of cryotherapy vs radiotherapy, but both evaluated whole-gland instead of focal cryotherapy, and found no randomized controlled trials of high-intensity focused ultrasound vs radiotherapy.

Section Summary: Focal Treatment Overview

Systematic reviews have reported no published prospective, comparative evidence for focal ablation techniques vs current standard treatment of localized prostate cancer. The evidence consists of case series and noncomparative observational studies. Most studies were small with short follow-up. Data on clinical

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Focal Treatments for Prostate Cancer

Policy # 00484

Original Effective Date: 12/16/2015

Current Effective Date: 12/20/2017

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.

Laser Ablation

Additional case series and nonrandomized studies have assessed of focal laser ablation since the Valerio review. Studies were small (range, 8-25 men), single arm, lacked long-term follow-up (range, 3-6 months) and did not report clinical outcomes (eg, progression-free survival, overall survival).

Cryoablation

The Cryo Online Data Registry is a database established and supported by a cryotherapy manufacturer. The data are maintained independently. Physicians submit standardized forms to the database and participation is voluntary. The registry contains case report forms of pretreatment and posttreatment information for patients undergoing whole-gland or partial-gland (focal) prostate cryoablation. Patients are stratified into low-, intermediate-, and high-risk groups. Ward and Jones have described characteristics of the focal cryotherapy registry patients in 2012. Biochemical success was defined using the ASTRO definitions. The analysis included 1160 patients treated with focal cryoablation and 5853 treated with whole-gland cryoablation between 1997 and 2007. Report of use of focal cryoablation increased dramatically between 1999 (46 reports) and 2005 (567 reports, $p < 0.01$). The biochemical success at 36 months for focal cryotherapy was 75.7% and was similar to that of whole-gland cryoablation (75.5%); no significant differences between biochemical success for whole-gland and focal cryoablation were observed for low-, intermediate-, or high-risk groups (p value not given). Urinary continence was 98.4% in focal and 96.9% in whole-gland cryoablation.

A matched cohort study published in 2015 included 317 men who underwent focal cryoablation with 317 men who underwent whole-gland cryoablation. Patients were entered into the Cryo Online Data Registry between 2007 and 2013. The Median (standard definition) age at the time of the procedure was 66 (7) years, and median follow-up was 58 months. All patients were preoperatively potent men who had low-risk disease according to the D'Amico risk criteria and were matched by age at surgery. Outcomes included biochemical recurrence-free survival (BRFS), defined using ASTRO and Phoenix criteria and assessed by Kaplan-Meier curves. Only patients with PSA nadir data were included in oncologic outcome analysis. Functional outcomes were assessed at 6, 12, and 24 months after the procedure for erectile function (defined as the ability to have intercourse with or without erectile aids), urinary continence, urinary retention, and rates of fistula formation. After surgery, 30% ($n=95$) and 17% ($n=55$) of the men who underwent whole-gland cryoablation and focal cryoablation, respectively, underwent biopsy, with positive biopsy rates of 12% and 14%, respectively. BRFS rates at 60 months using the Phoenix definition were 80% and 71% in the whole-gland and focal therapy cohorts, respectively, with a hazard ratio of 0.827 ($p > 0.1$). Using the ASTRO definition, BRFS rates were 82% and 73%, respectively ($p > 0.1$). Erectile function data at 24 months were available for 172 whole-gland and 160 focal therapy-treated men. Recovery of erectile function was achieved in 47% and 69% of patients in the whole-gland and focal therapy cohorts, respectively ($p = 0.001$). Urinary function data at 24 months were available for 307 whole-gland and 313 focal therapy patients. Urinary continence rates were 99% and 100% for the whole-gland and focal therapy groups, respectively.

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Focal Treatments for Prostate Cancer

Policy # 00484

Original Effective Date: 12/16/2015

Current Effective Date: 12/20/2017

($p=0.02$). Urinary retention rates at 6, 12, and 24 months were reported as 7%, 2%, and 0.6%, respectively, in the whole-gland treated patients vs 5%, 1%, and 0.9%, respectively, in the focal therapy cohort. One fistula was reported in each group.

In 2016, Lian et al reported on long-term results of a case series of 40 low- to intermediate-risk patients treated with primary focal cryoablation between 2006 and 2013 by a single urologist in China. Biochemical recurrence was defined using the Phoenix definition, and treatment failure was defined as at least 1 positive biopsy or biochemical recurrence. Mean follow-up was 63 months (range, 12-92 months). Two (5%) of 40 patients met the criteria for biochemical failure and 4 (10%) patients experienced treatment failure. Of the men who were potent before cryotherapy, 20 (77%) remained potent after treatment. Ninety-eight percent of the men were completely continent during follow-up.

Section Summary: Cryoablation

Data from the Cryo Online Data registry comparing focal with whole-gland cryoablation have suggested that BRFS is similar, although perhaps slightly lower in focal cryoablation compared with whole-gland cryoablation while erectile function preservation was higher.

PHOTODYNAMIC THERAPY

Preliminary results from a trial of TOOKAD, a soluble vascular-targeted photodynamic therapy (VTP), were presented in 2016 at the 31st Annual European Association of Urology Congress but have not yet been published. A total of 413 men with low-risk prostate cancer were randomized and followed for 2 years (206 in VTP plus active surveillance; 207 in active surveillance without VTP). It was reported that 28% of the patients in the VTP group and 58% of the control group experienced disease progression (hazard ratio, 0.34; 95% confidence interval, 0.24 to 0.46; $p<0.001$) and more patients in the VTP group (49%) and surveillance group (14%) had negative biopsies at 2 years.

Additional nonrandomized studies have assessed of photodynamic therapy since the Valerio review. A prospective, multicenter phase 2/3 trial by Taneja et al (2016) treated 30 men using photodynamic therapy. Follow-up was limited to 6 months, and trialists did not report important clinical outcomes (eg, progression-free survival, overall survival).

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 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

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Focal Treatments for Prostate Cancer

Policy # 00484

Original Effective Date: 12/16/2015

Current Effective Date: 12/20/2017

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.

References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "Focal Treatments for Prostate Cancer", Policy 8.01.61, 9:2017.
2. Dall'Era MA, Cooperberg MR, Chan JM, et al. Active surveillance for early-stage prostate cancer: review of the current literature. *Cancer*. Apr 15 2008;112(8):1650-1659. PMID 18306379
3. Bangma CH, Roemeling S, Schroder FH. Overdiagnosis and overtreatment of early detected prostate cancer. *World J Urol*. Mar 2007;25(1):3-9. PMID 17364211
4. Johansson JE, Andren O, Andersson SO, et al. Natural history of early, localized prostate cancer. *JAMA*. Jun 9 2004;291(22):2713-2719. PMID 15187052
5. Ploussard G, Epstein JI, Montironi R, et al. The contemporary concept of significant versus insignificant prostate cancer. *Eur Urol*. Aug 2011;60(2):291-303. PMID 21601982
6. Harnden P, Naylor B, Shelley MD, et al. The clinical management of patients with a small volume of prostatic cancer on biopsy: what are the risks of progression? A systematic review and meta-analysis. *Cancer*. Mar 1 2008;112(5):971-981. PMID 18186496
7. Brimo F, Montironi R, Egevad L, et al. Contemporary grading for prostate cancer: implications for patient care. *Eur Urol*. May 2013;63(5):892-901. PMID 23092544
8. Eylert MF, Persad R. Management of prostate cancer. *Br J Hosp Med (Lond)*. Feb 2012;73(2):95-99. PMID 22504752
9. Eastham JA, Kattan MW, Fearn P, et al. Local progression among men with conservatively treated localized prostate cancer: results from the Transatlantic Prostate Group. *Eur Urol*. Feb 2008;53(2):347-354. PMID 17544572
10. Bill-Axelsson A, Holmberg L, Ruutu M, et al. Radical prostatectomy versus watchful waiting in early prostate cancer. *N Engl J Med*. May 12 2005;352(19):1977-1984. PMID 15888698
11. Thompson IM, Jr., Goodman PJ, Tangen CM, et al. Long-term survival of participants in the prostate cancer prevention trial. *N Engl J Med*. Aug 15 2013;369(7):603-610. PMID 23944298
12. Albertsen PC, Hanley JA, Fine J. 20-year outcomes following conservative management of clinically localized prostate cancer. *JAMA*. May 4 2005;293(17):2095-2101. PMID 15870412
13. Borley N, Feneley MR. Prostate cancer: diagnosis and staging. *Asian J Androl*. Jan 2009;11(1):74-80. PMID 19050692
14. Freedland SJ. Screening, risk assessment, and the approach to therapy in patients with prostate cancer. *Cancer*. Mar 15 2011;117(6):1123-1135. PMID 20960523
15. Ip S, IJ D, Chung M, et al. An evidence review of active surveillance in men with localized prostate cancer. Evidence Report/Technology Assessment no. 204 (Prepared by Tufts Evidence-based Practice Center under Contract No. HHS 290-2007-10055-I). 2011; AHRQ Publication No. 12-E003-EF, Rockville, MD: Agency for Research and Quality.
16. Thompson I, JB T, Aus G ea. American Urological Association guideline for management of clinically localized prostate cancer: 2007 update. 2007; <http://www.auanet.org/common/pdf/education/clinical-guidance/Prostate-Cancer.pdf>. Accessed July 16, 2015.
17. Whitson JM, Carroll PR. Active surveillance for early-stage prostate cancer: defining the triggers for intervention. *J Clin Oncol*. Jun 10 2010;28(17):2807-2809. PMID 20439633
18. Albertsen PC. Treatment of localized prostate cancer: when is active surveillance appropriate? *Nat Rev Clin Oncol*. Jul 2010;7(7):394-400. PMID 20440282
19. Jacome-Pita F, Sanchez-Salas R, Barret E, et al. Focal therapy in prostate cancer: the current situation. *Ecancermedalscience*. 2014;8:435. PMID 24944577
20. Nguyen CT, Jones JS. Focal therapy in the management of localized prostate cancer. *BJU Int*. May 2011;107(9):1362-1368. PMID 21223478

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Focal Treatments for Prostate Cancer

Policy # 00484

Original Effective Date: 12/16/2015

Current Effective Date: 12/20/2017

21. Lindner U, Lawrentschuk N, Schatloff O, et al. Evolution from active surveillance to focal therapy in the management of prostate cancer. *Future Oncol.* Jun 2011;7(6):775-787. PMID 21675840
22. Iberti CT, Mohamed N, Palese MA. A review of focal therapy techniques in prostate cancer: clinical results for high-intensity focused ultrasound and focal cryoablation. *Rev Urol.* 2011;13(4):e196-202. PMID 22232569
23. Lecornet E, Ahmed HU, Moore CM, et al. Conceptual basis for focal therapy in prostate cancer. *J Endourol.* May 2010;24(5):811-818. PMID 20443699
24. Tay KJ, Mendez M, Moul JW, et al. Active surveillance for prostate cancer: can we modernize contemporary protocols to improve patient selection and outcomes in the focal therapy era? *Curr Opin Urol.* Mar 12 2015. PMID 25768694
25. Passoni NM, Polascik TJ. How to select the right patients for focal therapy of prostate cancer? *Curr Opin Urol.* May 2014;24(3):203-208. PMID 24625428
26. Scales CD, Jr., Presti JC, Jr., Kane CJ, et al. Predicting unilateral prostate cancer based on biopsy features: implications for focal ablative therapy--results from the SEARCH database. *J Urol.* Oct 2007;178(4 Pt 1):1249-1252. PMID 17698131
27. Mouraviev V, Mayes JM, Sun L, et al. Prostate cancer laterality as a rationale of focal ablative therapy for the treatment of clinically localized prostate cancer. *Cancer.* Aug 15 2007;110(4):906-910. PMID 17587207
28. Mouraviev V, Mayes JM, Madden JF, et al. Analysis of laterality and percentage of tumor involvement in 1386 prostatectomized specimens for selection of unilateral focal cryotherapy. *Technol Cancer Res Treat.* Apr 2007;6(2):91-95. PMID 17375971
29. Muto S, Yoshii T, Saito K, et al. Focal therapy with high-intensity-focused ultrasound in the treatment of localized prostate cancer. *Jpn J Clin Oncol.* Mar 2008;38(3):192-199. PMID 18281309
30. Kasivisvanathan V, Emberton M, Ahmed HU. Focal therapy for prostate cancer: rationale and treatment opportunities. *Clin Oncol (R Coll Radiol).* Aug 2013;25(8):461-473. PMID 23759249
31. Mouraviev V, Villers A, Bostwick DG, et al. Understanding the pathological features of focality, grade and tumour volume of early-stage prostate cancer as a foundation for parenchyma-sparing prostate cancer therapies: active surveillance and focal targeted therapy. *BJU Int.* Oct 2011;108(7):1074-1085. PMID 21489116
32. Mouraviev V, Mayes JM, Polascik TJ. Pathologic basis of focal therapy for early-stage prostate cancer. *Nat Rev Urol.* Apr 2009;6(4):205-215. PMID 19352395
33. Liu W, Laitinen S, Khan S, et al. Copy number analysis indicates monoclonal origin of lethal metastatic prostate cancer. *Nat Med.* May 2009;15(5):559-565. PMID 19363497
34. Guo CC, Wang Y, Xiao L, et al. The relationship of TMPRSS2-ERG gene fusion between primary and metastatic prostate cancers. *Hum Pathol.* May 2012;43(5):644-649. PMID 21937078
35. Ahmed HU, Emberton M. Active surveillance and radical therapy in prostate cancer: can focal therapy offer the middle way? *World J Urol.* Oct 2008;26(5):457-467. PMID 18704441
36. Stamey TA, Freiha FS, McNeal JE, et al. Localized prostate cancer. Relationship of tumor volume to clinical significance for treatment of prostate cancer. *Cancer.* Feb 1 1993;71(3 Suppl):933-938. PMID 7679045
37. Nelson BA, Shappell SB, Chang SS, et al. Tumour volume is an independent predictor of prostate-specific antigen recurrence in patients undergoing radical prostatectomy for clinically localized prostate cancer. *BJU Int.* Jun 2006;97(6):1169-1172. PMID 16686706
38. van den Bos W, Muller BG, Ahmed H, et al. Focal therapy in prostate cancer: international multidisciplinary consensus on trial design. *Eur Urol.* Jun 2014;65(6):1078-1083. PMID 24444476
39. Mayes JM, Mouraviev V, Sun L, et al. Can the conventional sextant prostate biopsy accurately predict unilateral prostate cancer in low-risk, localized, prostate cancer? *Urol Oncol.* Mar-Apr 2011;29(2):166-170. PMID 19451000
40. Sinnott M, Falzarano SM, Hernandez AV, et al. Discrepancy in prostate cancer localization between biopsy and prostatectomy specimens in patients with unilateral positive biopsy: implications for focal therapy. *Prostate.* Aug 1 2012;72(11):1179-1186. PMID 22161896
41. Gallina A, Maccagnano C, Suardi N, et al. Unilateral positive biopsies in low risk prostate cancer patients diagnosed with extended transrectal ultrasound-guided biopsy schemes do not predict unilateral prostate cancer at radical prostatectomy. *BJU Int.* Jul 2012;110(2 Pt 2):E64-68. PMID 22093108
42. Briganti A, Tutolo M, Suardi N, et al. There is no way to identify patients who will harbor small volume, unilateral prostate cancer at final pathology. implications for focal therapies. *Prostate.* Jun 1 2012;72(8):925-930. PMID 21965006
43. Heidenreich A, Bastian PJ, Bellmunt J, et al. European Association of Urology 2012 guidelines on prostate cancer (available at: <http://www.uroweb.org/guidelines/online-guidelines/>). Accessed July 16, 2015.

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Focal Treatments for Prostate Cancer

Policy # 00484

Original Effective Date: 12/16/2015

Current Effective Date: 12/20/2017

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
45. Hu Y, Ahmed HU, Carter T, et al. A biopsy simulation study to assess the accuracy of several transrectal ultrasonography (TRUS)-biopsy strategies compared with template prostate mapping biopsies in patients who have undergone radical prostatectomy. *BJU Int*. Sep 2012;110(6):812-820. PMID 22394583
46. Tsivian M, Abern MR, Qi P, et al. Short-term functional outcomes and complications associated with transperineal template prostate mapping biopsy. *Urology*. Jul 2013;82(1):166-170. PMID 23697794
47. Arumainayagam N, Ahmed HU, Moore CM, et al. Multiparametric MR imaging for detection of clinically significant prostate cancer: a validation cohort study with transperineal template prostate mapping as the reference standard. *Radiology*. Sep 2013;268(3):761-769. PMID 23564713
48. Dickinson L, Ahmed HU, Allen C, et al. Magnetic resonance imaging for the detection, localisation, and characterisation of prostate cancer: recommendations from a European consensus meeting. *Eur Urol*. Apr 2011;59(4):477-494. PMID 21195536
49. National Institute for Health and Care Excellence (NICE). Focal Therapy Using Cryoablation for Localised Prostate Cancer (IPG423). 2012; <https://www.nice.org.uk/guidance/ipg423/chapter/1-guidance>. Accessed July 16, 2015.
50. National Institute for Health and Care Excellence (NICE). Focal Therapy Using High-Intensity Focused Ultrasound for Localized Prostate Cancer (IPG424). 2012; <http://www.nice.org.uk/guidance/ipg424>. Accessed July 16, 2015.
51. Lee T, Mendhiratta N, Sperling D, et al. Focal laser ablation for localized prostate cancer: principles, clinical trials, and our initial experience. *Rev Urol*. 2014;16(2):55-66. PMID 25009445
52. Valerio M, Ahmed HU, Emberton M, et al. The role of focal therapy in the management of localised prostate cancer: a systematic review. *Eur Urol*. Oct 2014;66(4):732-751. PMID 23769825
53. Liberati A, Altman DG, Tetzlaff J, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration. *J Clin Epidemiol*. Oct 2009;62(10):e1-34. PMID 19631507
54. Roach M, 3rd, Hanks G, Thames H, Jr., et al. Defining biochemical failure following radiotherapy with or without hormonal therapy in men with clinically localized prostate cancer: recommendations of the RTOG-ASTRO Phoenix Consensus Conference. *Int J Radiat Oncol Biol Phys*. Jul 15 2006;65(4):965-974. PMID 16798415
55. Wolff RF, Ryder S, Bossi A, et al. A systematic review of randomised controlled trials of radiotherapy for localised prostate cancer. *Eur J Cancer*. Nov 2015;51(16):2345-2367. PMID 26254809
56. Lepor H, Llukani E, Sperling D, et al. Complications, recovery, and early functional outcomes and oncologic control following in-bore focal laser ablation of prostate cancer. *Eur Urol*. Dec 2015;68(6):924-926. PMID 25979568
57. Natarajan S, Raman S, Priester AM, et al. Focal laser ablation of prostate cancer: phase I clinical trial. *J Urol*. Jul 2016;196(1):68-75. PMID 26748164
58. Ward JF, Jones JS. Focal cryotherapy for localized prostate cancer: a report from the national Cryo On-Line Database (COLD) Registry. *BJU Int*. Jun 2012;109(11):1648-1654. PMID 22035200
59. Mendez MH, Passoni NM, Pow-Sang J, et al. Comparison of Outcomes Between Preoperatively Potent Men Treated with Focal Versus Whole Gland Cryotherapy in a Matched Population. *J Endourol*. Jul 13 2015. PMID 26058496
60. Lian H, Zhuang J, Yang R, et al. Focal cryoablation for unilateral low-intermediate-risk prostate cancer: 63-month mean follow-up results of 41 patients. *Int Urol Nephrol*. Jan 2016;48(1):85-90. PMID 26531063
61. Emberton M. **TOOKAD (Padeliporfin) Vascular-Targeted Photodynamic Therapy Versus Active Surveillance in Men With Low Risk Prostate Cancer. A Randomized Phase 3 Clinical Trial (Abstract LBA02).** Paper presented at: 31st Annual European Association of Urology Congress; 2016, March 13; Munich, Germany.
62. Taneja SS, Bennett J, Coleman J, et al. Final results of a phase I/II multicenter trial of WST11 vascular targeted photodynamic therapy for hemi-ablation of the prostate in men with unilateral low risk prostate cancer performed in the United States. *J Urol*. Jun 9 2016. PMID 27291652
63. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: prostate cancer. Version 3.2016. https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed August 8, 2016.
64. National Institute for Health and Care Excellence (NICE). Prostate cancer: diagnosis and management (CG175). 2014; <https://www.nice.org.uk/guidance/cg175/resources/prostate-cancer-diagnosis-and-management-35109753913285>. Accessed August 8, 2016.
65. American Urological Association (AUA). Guideline for the Management of Clinically Localized Prostate Cancer. 2011; <https://www.auanet.org/education/guidelines/prostate-cancer.cfm>. Accessed July 16, 2015.

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Focal Treatments for Prostate Cancer

Policy # 00484
 Original Effective Date: 12/16/2015
 Current Effective Date: 12/20/2017

- 66. National Cancer Institute. Prostate Cancer Treatment, Treatment Option Overview. 2015; http://www.cancer.gov/cancertopics/pdq/treatment/prostate/Patient/page4#_172. Accessed July 16, 2015.
- 67. Sanda MG, Chen RC, Crispino T, et al. Clinically Localized Prostate Cancer: AUA/ASTRO/SUO Guideline. 2017; [http://www.auanet.org/guidelines/clinically-localized-prostate-cancer-new-\(aua/astro/suo-guideline-2017\)](http://www.auanet.org/guidelines/clinically-localized-prostate-cancer-new-(aua/astro/suo-guideline-2017)). Accessed August 30, 2017.

Policy History

Original Effective Date: 12/16/2015
 Current Effective Date: 12/20/2017
 12/03/2015 Medical Policy Committee review
 12/16/2015 Medical Policy Implementation Committee approval. New Policy.
 12/01/2016 Medical Policy Committee review
 12/21/2016 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
 01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
 12/07/2017 Medical Policy Committee review
 12/20/2017 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
 Next Scheduled Review Date: 12/2018

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)†, copyright 2016 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	53852, 53899, 55873, 55899, 96570, 96571
HCPCS	C2618, J9600 Code added eff 7/1/2017: C9747
ICD-10 Diagnosis	C61

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Focal Treatments for Prostate Cancer

Policy # 00484

Original Effective Date: 12/16/2015

Current Effective Date: 12/20/2017

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. FDA and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.