LOUISIANA BLUE

Focal Treatments for Prostate Cancer

Policy # 00484
Original Effective Date: 12/16/2015
Current Effective Date: 01/01/2025

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.

Note: Magnetic Resonance-Guided Focused Ultrasound is addressed separately in medical policy 00180.

Note: Saturation Biopsy for Diagnosis, Staging, and Management of Prostate Cancer is addressed separately in medical policy 00639.

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 individuals with localized prostate cancer to be **investigational.***

Background/Overview

Prostate Cancer

Prostate cancer is the second most common cancer diagnosed among men in the U.S. According to the National Cancer Institute, nearly 268,490 new cases are estimated to be diagnosed in the U.S. in 2022, associated with around 34,500 deaths. Prostate cancer is more likely to develop in older men and in non-Hispanic Black men. About 6 in 10 cases are diagnosed in men who are ≥65 years of age, and it is rare in men <40 years of age. 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, the National Cancer Institute Surveillance Epidemiology and End Results Program data have shown that age-adjusted cancer-specific mortality rates for men with prostate cancer declined from 40 per 100,000 in 1992 to 19 per 100,000 in 2018. This decline has been attributed to a combination of earlier detection via PSA screening and improved therapies.

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.

Modalities Used to Ablate Lesions
The following ablative methods for which clinical evidence is available are considered herein: focal laser ablation; high-intensity focused ultrasound (HIFU); cryoablation; radiofrequency ablation (RFA); photodynamic therapy and irreversible electroporation. 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. This medical policy does not cover focal brachytherapy.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
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 MRI 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. FDA product code: LLZ, GEX, FRN.

High-Intensity Focused Ultrasound
In October 2015, the Sonablate®‡ 450 (SonaCare Medical) was cleared for marketing through the 510(k) process after approval of a de novo request and classification 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 U.S. 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 the FDA through the 510(k) process for cryoablation of the prostate include Visual-ICE®‡ (Galil Medical), Ice Rod CX, CryoCare®‡ (Galil Medical), IceSphere (Galil Medical), and Cryocare®‡ Systems (Endocare®‡; HealthTronics). FDA product code: GEH.

Radiofrequency Ablation
Radiofrequency ablation 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. porfimer sodium (Photofrin®‡; Axcan Pharma) and psoralen are photosensitizer ultraviolet lamps used to treat cancer; they were cleared for marketing by the FDA through the 510(k) process. FDA product code: FTC.

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.

Magnetic Nanoparticles
MagForce®‡ USA, Inc. is conducting a clinical study evaluating NanoTherm®‡ under an FDA Investigational Device Exemption (IDE) (NCT05010759). NanoTherm uses magnetic nanoparticles and an alternating magnetic field to create heat and local ablation in the ablation of prostate cancer.

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.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Description
Prostate cancer is the second most common cancer diagnosis men receive in the U.S., and the behavior of localized prostate cancer can prove difficult to predict on a case-by-case basis. Most

men with prostate cancer undergo whole-gland treatments, which can often lead to substantial adverse events. To reduce tumor burden and minimize morbidity associated with radical treatment, investigators have developed a therapy known as focal treatment. Focal treatment seeks to ablate either an "index" lesion (defined as the largest cancerous lesion with the highest grade tumor), or alternatively, to ablate nonindex lesions and other areas where cancer has been known to occur. Addressed in this review are several ablative methods used to remove cancerous lesions in localized prostate cancer (eg, focal laser ablation, high-intensity focused ultrasound [HIFU], cryoablation, radiofrequency ablation [RFA], photodynamic therapy, irreversible electroporation).

Summary of Evidence

For individuals who have primary localized prostate cancer who receive focal therapy using laser ablation, HIFU, cryoablation, RFA, photodynamic therapy, or irreversible electroporation, the evidence includes systematic reviews, studies from a registry cohort, and numerous observational studies. Relevant outcomes are overall survival (OS), disease-specific survival, symptoms, change in disease status, functional outcomes, quality of life (QoL), 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, 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 OS 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 that the technology results in an improvement in the net health outcome.

Supplemental Information

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Urological Association et al

The American Urological Association, in collaboration with the American Society for Radiation Oncology (ASTRO) with additional representation from the American Society of Clinical Oncology (ASCO), and Society of Urologic Oncology (SUO) published updated guidelines on the management of clinically localized prostate cancer in 2022. The guidelines included the following recommendation on focal treatments:

- "Clinicians should inform patients with intermediate-risk prostate cancer considering whole gland or focal ablation that there are a lack of high-quality data comparing ablation outcomes to radiation therapy, surgery, and active surveillance. (Expert Opinion)"
- "Clinicians should not recommend whole gland or focal ablation for patients with high-risk prostate cancer outside of a clinical trial. (Expert Opinion)"

National Comprehensive Cancer Network
The National Comprehensive Cancer Network (NCCN) guidelines for prostate cancer (v4.2024) recommend only cryosurgery and high-intensity focused ultrasound (HIFU) as local therapy options for radiotherapy *recurrence* in the absence of metastatic disease (category 2B). Cryotherapy or other local therapies are not recommended as routine *primary* therapy for localized prostate cancer due to lack of long-term data comparing these treatments to radiation or radical prostatectomy.

National Cancer Institute
The National Cancer Institute (NCI; 2023) updated its information on prostate cancer treatments. The NCI indicated that cryoablation, photodynamic therapy, and HIFU were new treatment options currently being studied in national trials. The NCI offered no recommendation for or against these treatments.

National Institute for Health and Care Excellence
The National Institute for Health and Care Excellence (2019; updated in 2021) issued guidance on management for localized prostate cancer. Cryoablation and high-intensity ultrasound are not recommended for the treatment of localized prostate cancer because there is a lack of evidence on quality of life benefits and long-term survival.

U.S. Preventive Services Task Force Recommendations
The U.S. Preventive Services Task Force published recommendations for prostate cancer screening.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

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

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05454488	An Evidence-Based Focal Cryotherapy Protocol for Focal Ablation of Intermediate Risk Prostate Cancer	30	Jan 2024

NCT04972097	Pivotal Study of the NanoKnife System for the Ablation of Prostate Tissue (PRESERVE)	121	Jul 2024
NCT04045756	Short-term Efficacy of Transperineal Laser Ablation (TPLA) with Image Fusion and Multi-parametric (mpMRI) Follow-up in Focal Low-intermediate Risk Prostate Cancer: Interventional Pilot Study	50	Aug 2024
NCT03668652	A Randomized Control Trial of Focal Prostate Ablation Versus Radical Prostatectomy	200	Sep 2024
NCT01835977	Multi-Center Randomized Clinical Trial Irreversible Electroporation for the Ablation of Localized Prostate Cancer	106	Jan 2025
NCT03568188	Phase 2, Multicenter, Prospective Cohort Study, Estimating the Efficacy of Focused HIFU Therapy in Patients with Localized Intermediate Risk Prostate Cancer	170	Sep 2025
NCT03531099	Phase 3, Multicenter, Randomized Study, Evaluating the Efficacy and Tolerability of Focused HIFU Therapy Compared to Active Surveillance in Patients With Significant Low Risk Prostate Cancer	108	Oct 2026
NCT04049747	Imperial Prostate 4: Comparative Health Research Outcomes of NOvel Surgery in Prostate Cancer	2450	May 2027
NCT05610852	Prospective Single-Center Randomized Study Of Single-Port Transvesical Partial Prostatectomy Versus High Intensity Focused Ultrasound (HIFU)	276	Jul 2028
NCT04549688	Active Surveillance Plus (AS+): Local Tumor Control with High-intensity Focused Ultrasound (HIFU) in Patients with Localized Prostate Cancer	250	Sep 2030
NCT06223295	Effectiveness of Focal Therapy in Men With Prostate Cancer (ENFORCE)	356	Feb 2031
NCT06451445	A Pan-Canadian, Investigator Initiated Clinical Trial With Focal IRE Directed to Intermediate-Risk Prostate Cancer (WIRED)	100	May 2032
NCT05027477	Customized Ablation of the Prostate With the TULSA Procedure Against Radical Prostatectomy Treatment: a Randomized Controlled Trial for Localized Prostate Cancer (CAPTAIN)	201	Dec 2032

Unpublished		276	Jul 2028
NCT04307056	Evaluation of high intensity focused ultrasound (hifu) in curative treatment of localized prostate cancer at low or intermediate risk and in treatment of recurrence after radiotherapy	3862	Aug 2022 (completed)

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

References

1. American Cancer Society. Key statistics for prostate cancer. January 12, 2022. https://www.cancer.org/cancer/prostate-cancer/about/key-statistics.html.
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): 1650-9. PMID 18306379
3. Jácome-Pita F, Sánchez-Salas R, Barret E, et al. Focal therapy in prostate cancer: the current situation. Ecancermedicalscience. 2014; 8: 435. PMID 24944577
4. Nguyen CT, Jones JS. Focal therapy in the management of localized prostate cancer. BJU Int. May 2011; 107(9): 1362-8. PMID 21223478
5. 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): 775-87. PMID 21675840
6. 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
7. Lecornet E, Ahmed HU, Moore CM, et al. Conceptual basis for focal therapy in prostate cancer. J Endourol. May 2010; 24(5): 811-8. PMID 20443699
8. 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): 192-9. PMID 18281309
9. Kasivisvanathan V, Emberton M, Ahmed HU. Focal therapy for prostate cancer: rationale and treatment opportunities. Clin Oncol (R Coll Radiol). Aug 2013; 25(8): 461-73. PMID 23759249
10. 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): 559-65. PMID 19363497
11. 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): 457-67. PMID 18704441
12. 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): 1078-83. PMID 24444476
13. National Institute for Health and Care Excellence (NICE). Prostate cancer: diagnosis and management. [NG131]. 2019; https://www.nice.org.uk/guidance/ng131/chapter/Recommendations.

14. National Institute for Health and Care Excellence (NICE). Focal Therapy Using High-Intensity Focused Ultrasound for Localized Prostate Cancer [IPG424]. 2012; https://www.nice.org.uk/guidance/ipg424.
15. Bangma CH, Roemeling S, Schröder FH. Overdiagnosis and overtreatment of early detected prostate cancer. World J Urol. Mar 2007; 25(1): 3-9. PMID 17364211
16. Johansson JE, Andrén O, Andersson SO, et al. Natural history of early, localized prostate cancer. JAMA. Jun 09 2004; 291(22): 2713-9. PMID 15187052
17. 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
18. 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 01 2008; 112(5): 971-81. PMID 18186496
19. 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
20. Eylert MF, Persad R. Management of prostate cancer. Br J Hosp Med (Lond). Feb 2012; 73(2): 95-9. PMID 22504752
21. 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): 347-54. PMID 17544572
22. Bill-Axelson 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): 1977-84. PMID 15888698
23. Thompson IM, 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): 603-10. PMID 23944298
24. Albertsen PC, Hanley JA, Fine J. 20-year outcomes following conservative management of clinically localized prostate cancer. JAMA. May 04 2005; 293(17): 2095-101. PMID 15870412
25. 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. May 2015; 25(3): 185-90. PMID 25768694
26. Passoni NM, Polascik TJ. How to select the right patients for focal therapy of prostate cancer?. Curr Opin Urol. May 2014; 24(3): 203-8. PMID 24625428
27. Scales CD, Presti JC, 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): 1249-52. PMID 17698131
28. 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): 906-10. PMID 17587207
29. 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): 91-5. PMID 17375971
30. 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): 1074-85. PMID 21489116

31. Mouraviev V, Mayes JM, Polascik TJ. Pathologic basis of focal therapy for early-stage prostate cancer. Nat Rev Urol. Apr 2009; 6(4): 205-15. PMID 19352395
32. 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): 644-9. PMID 21937078
33. 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 01 1993; 71(3 Suppl): 933-8. PMID 7679045
34. 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): 1169-72. PMID 16686706
35. 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. 2011; 29(2): 166-70. PMID 19451000
36. 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 01 2012; 72(11): 1179-86. PMID 22161896
37. 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): E64-8. PMID 22093108
38. 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 01 2012; 72(8): 925-30. PMID 21965006
39. 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): 761-9. PMID 23564713
40. 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): 477-94. PMID 21195536
41. 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
42. 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
43. Borley N, Feneley MR. Prostate cancer: diagnosis and staging. Asian J Androl. Jan 2009; 11(1): 74-80. PMID 19050692
44. Freedland SJ. Screening, risk assessment, and the approach to therapy in patients with prostate cancer. Cancer. Mar 15 2011; 117(6): 1123-35. PMID 20960523
45. Ip S, Dahabreh IJ, Chung M, et al. An evidence review of active surveillance in men with localized prostate cancer. Evidence Report/Technology Assessment no. 204 (AHRQ Publication No. 12-E003-EF). Rockville, MD: Agency for Research and Quality; 2011.

46. American Urological Association. Guideline for management of clinically localized prostate cancer: 2007 update. Linthicum, MD: American Urological Association Education and Research; 2007.
47. Eastham JA, Auffenberg GB, Barocas DA, et al. Clinically Localized Prostate Cancer: AUA/ASTRO Guideline. 2022; https://www.auanet.org/guidelines/guidelines/clinically-localized-prostate-cancer-aua/astro-guideline-2022.
48. Whitson JM, Carroll PR. Active surveillance for early-stage prostate cancer: defining the triggers for intervention. J Clin Oncol. Jun 10 2010; 28(17): 2807-9. PMID 20439633
49. Albertsen PC. Treatment of localized prostate cancer: when is active surveillance appropriate?. Nat Rev Clin Oncol. Jul 2010; 7(7): 394-400. PMID 20440282
50. Muller BG, van den Bos W, Brausi M, et al. Follow-up modalities in focal therapy for prostate cancer: results from a Delphi consensus project. World J Urol. Oct 2015; 33(10): 1503-9. PMID 25559111
51. 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
52. Azzouzi AR, Vincendeau S, Barret E, et al. Padeliporfin vascular-targeted photodynamic therapy versus active surveillance in men with low-risk prostate cancer (CLIN1001 PCM301): an open-label, phase 3, randomised controlled trial. Lancet Oncol. Feb 2017; 18(2): 181-191. PMID 28007457
53. Bates AS, Ayers J, Kostakopoulos N, et al. A Systematic Review of Focal Ablative Therapy for Clinically Localised Prostate Cancer in Comparison with Standard Management Options: Limitations of the Available Evidence and Recommendations for Clinical Practice and Further Research. Eur Urol Oncol. Jun 2021; 4(3): 405-423. PMID 33423943
54. Hopstaken JS, Bomers JGR, Sedelaar MJP, et al. An Updated Systematic Review on Focal Therapy in Localized Prostate Cancer: What Has Changed over the Past 5 Years?. Eur Urol. Jan 2022; 81(1): 5-33. PMID 34489140
55. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: prostate cancer. Version 4.2022. https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf.
56. National Cancer Institute. Prostate Cancer Treatment (PDQ)Patient Version: Treatment Option Overview. 2021. https://www.cancer.gov/types/prostate/patient/prostate-treatment-pdq#link/_142.
57. U.S. Preventive Services Task Force. Final Recommendation Statement: Prostate Cancer: Screening. 2018; https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/prostate- cancer-screening1.

Policy History

Original Effective Date: 12/16/2015
Current Effective Date: 01/01/2025
12/03/2015 Medical Policy Committee review

Policy # 00484
Original Effective Date: 12/16/2015
Current Effective Date: 01/01/2025

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.
12/06/2018	Medical Policy Committee review
12/19/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2019	Coding update
12/05/2019	Medical Policy Committee review
12/11/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged. Coding update.
12/03/2020	Medical Policy Committee review
12/09/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/02/2021	Medical Policy Committee review
12/08/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/01/2022	Medical Policy Committee review
12/06/2022	Coding update
12/14/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/07/2023	Medical Policy Committee review
12/13/2023	Medical Policy Implementation Committee approval. Removed photodynamic therapy from body of policy. Body of the policy updated. Coverage eligibility unchanged.
12/05/2024	Medical Policy Committee review
12/11/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged. Coding update 01/01/2025.

Next Scheduled Review Date: 12/2025

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2023 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 Louisiana Blue Medical Policy Coverage Guidelines is with Louisiana Blue 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 Louisiana Blue 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 Louisiana Blue 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	0582T, 0655T, 0738T, 0739T 53852, 53854, 53899, 55873, 55880, 55899 Add codes effective 01/01/2025: 0600T, 0601T, 51721, 55881, 55882
HCPCS	C2618
ICD-10 Diagnosis	C61

*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. Food and Drug Administration (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 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.

Policy # 00484
Original Effective Date: 12/16/2015
Current Effective Date: 01/01/2025

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

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.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.