

MEDICAL POLICY – 8.01.541

Focal Treatments for Prostate Cancer

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RELATED MEDICAL POLICIES:

2.01.544 Transurethral Water Vapor Thermal Therapy and Transurethral Water Jet Ablation for Benign Prostatic Hyperplasia
6.01.68 Irreversible Electroporation of Tumors Located in the Liver, Pancreas, Kidney, or Lung, or Prostate
7.01.109 Magnetic Resonance–Guided Focused Ultrasound

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[POLICY CRITERIA](#) | [CODING](#) | [RELATED INFORMATION](#)
[EVIDENCE REVIEW](#) | [REFERENCES](#) | [HISTORY](#)



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Introduction

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

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

Policy Coverage Criteria

| Service | Investigational |
|---|--|
| Focal treatments for prostate cancer | <p>Use of any focal therapy modality to treat individuals with localized prostate cancer is investigational, including, but not limited to, any of the following treatments:</p> <ul style="list-style-type: none">• Focal laser ablation• High-intensity focused ultrasound• Cryoablation• Radiofrequency ablation• Photodynamic therapy <p>Note: Irreversible electroporation (e.g., Nanoknife) is addressed in a separate medical policy. See Related Policies.</p> |

Coding

| Code | Description |
|------------|---|
| CPT | |
| 0582T | Transurethral ablation of malignant prostate tissue by high-energy water vapor thermotherapy, including intraoperative imaging and needle guidance |
| 0655T | Transperineal focal laser ablation of malignant prostate tissue, including transrectal imaging guidance with MR-fused images or other enhanced ultrasound imaging |
| 0738T | Treatment planning for magnetic field induction ablation of malignant prostate tissue, using data from previously performed magnetic resonance imaging (MRI) examination |
| 0739T | Ablation of malignant prostate tissue by magnetic field induction, including all intraprocedural, transperineal needle/catheter placement for nanoparticle installation and intraprocedural temperature monitoring, thermal dosimetry, bladder irrigation, and magnetic field nanoparticle activation |
| 0950T | Ablation of benign prostate tissue, transrectal, with high intensity-focused ultrasound (HIFU), including ultrasound guidance (new code effective 07/01/25) |
| 55880 | Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound (HIFU), including ultrasound guidance |



| Code | Description |
|-------|---|
| 55899 | Unlisted procedure, male genital system |

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

N/A

Evidence Review

Description

Prostate cancer is the second most common cancer diagnosis men receive in the United States (US), 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 treatments, 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. This policy addresses several ablative methods used to remove cancerous lesions in localized prostate cancer (e.g., focal laser ablation, high-intensity focused ultrasound (HIFU), cryoablation, radiofrequency ablation (RFA), photodynamic therapy, irreversible electroporation).

Background

Prostate Cancer

Prostate cancer is the second most common cancer diagnosed among men in the US. According to the American Cancer Society, nearly 313,780 new cases are estimated to be diagnosed in the US in 2025 and associated with around 35,770 deaths.¹ 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.² The prostate cancer death rate declined by about half from 1993 to 2022, likely due to earlier detection and improved treatment.¹

Diagnosis

From a clinical standpoint, different types of localized prostate cancers may appear similar during initial diagnosis.¹⁵ However, prostate cancer often exhibits varying degrees of risk of progression that may not be captured by accepted clinical risk categories (e.g., D'Amico criteria) or prognostic tools based on clinical findings (e.g., PSA titers, Gleason grade, or tumor stage).¹⁶⁻²⁰ 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%^{21,22} to 20%²³ to perhaps 27% at 20-year follow-up.²⁴ 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 of 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.^{43,44} An individual may choose definitive treatment upfront.⁴⁵ Surgery (radical prostatectomy) or external beam radiotherapy are frequently used to treat individuals with localized prostate cancer.^{44,46} Complications most commonly reported with radical prostatectomy or external-beam radiotherapy and with the greatest variability are incontinence (0% to 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% to 39%); and erectile dysfunction, including impotence (50% to 90%).⁴⁶

American Urological Association guidelines state that for individuals with low-risk prostate cancer, clinicians should recommend active surveillance.⁴⁷ With this approach, individuals forego immediate therapy but continue regular monitoring until signs or symptoms of disease progression are evident — at which point curative treatment is instituted.^{48,49}



Focal Treatments of Localized Prostate Cancer

Given significant uncertainty in predicting the behavior of individual localized prostate cancers, and the substantial adverse effects associated with definitive treatments, investigators have sought a therapeutic middle ground. The latter seeks to minimize the 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.³⁻⁷

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.²⁵ Thus, the appropriate patient selection is imperative for physicians who must decide whether to recommend active surveillance or focal treatment for individuals who refuse radical therapy or for whom it is not recommended due to the risk/benefit balance.²⁶

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 individual.^{27,28,29} 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.⁸ While these approaches can be curative, the more extensive the treatment, the more likely the functional adverse outcomes would approach those of radical treatments.

The concept that clinically indolent lesions comprise most of the tumor burden in organ-confined prostate cancer led to the development of a lesion-targeted strategy, which is referred



to as “focal therapy” in this policy.⁹ 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 the clinical progression of disease.^{30,31} This concept is supported by molecular genetics evidence that suggests that a single index tumor focus is usually responsible for disease progression and metastasis.^{10,32} The index lesion approach leaves in place small foci less than 0.5 centimeter³ (cm) in volume, with a Gleason score less than 7, that are considered unlikely to progress over a 10- to 20-year period.^{11,33,34} 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 three activities (disease localization, focal ablation energy to the tumor, assessment of treatment effectiveness).^{9,26} Systematic transrectal ultrasound-guided biopsy alone has been investigated; however, it has been considered insufficient for patient selection or disease localization for focal therapy.^{12,35-38}

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 individuals and lesions for focal therapy.^{9,12,25} Evidence has shown mpMRI can detect high-grade, large prostate cancer foci with performance similar to transperineal prostate mapping using a brachytherapy template.³⁹ For example, for the primary end point definition (lesion, ≥ 4 millimeter [mm]; Gleason score, $\geq 3+4$), with transperineal prostate mapping 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 (e.g., mpMRI requires highly specialized MRI-compatible equipment, biopsy within the MRI scanner is challenging, interpretation of prostate MRI images requires experienced uroradiologists), and it is still necessary to histologically confirm suspicious lesions using transperineal prostate mapping.⁴⁰



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.^{3,4,6,7,8,9,10,11,12,13,14} 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 transperineally or transrectally into the cancer focus. The tissue is destroyed through the 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.⁴¹

High-Intensity Focused Ultrasound

High-intensity focused ultrasound (HIFU) 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 3x3x10 mm. The surgeon uses a transrectal probe to plan, perform, and monitor treatment in a real-time sequence to ablate the entire gland or small discrete lesions.

Cryoablation

Cryoablation induces cell death through direct cellular toxicity from disruption of the cell membrane caused by ice-ball crystals and vascular compromise from thrombosis and ischemia secondary to freezing below -30°C. Using a transperineal prostate mapping 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 (RFA) uses energy produced by a 50-watt generator at a frequency of 460 kHz. Energy is transmitted to the tumor focus through 15 needle electrodes inserted transperineally under ultrasound guidance. RFA produces an increase in tissue temperature causing coagulative necrosis.

Photodynamic Therapy

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 (i.e., 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 the assessment of necrosis and treatment progress.

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. The relevant outcomes are overall survival (OS), disease-specific survival, symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. The evidence is highly heterogeneous and inconsistently reports clinical outcomes. No prospective, comparative evidence was found for the majority of focal ablation techniques versus current standard treatment of localized prostate cancer, including radical prostatectomy, external-beam radiotherapy, 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 (e.g., 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.



Ongoing and Unpublished Clinical Trials

Some currently ongoing and 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 2026 |
| 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 |
| 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 2033 |
| NCT05027477 | Customized Ablation of the Prostate With the TULSA Procedure Against Radical Prostatectomy Treatment: a Randomized Controlled Trial for Localized Prostate Cancer (CAPTAIN) | 201 | Aug 2036 |
| Unpublished | | | |
| NCT04049747 | Imperial Prostate 4: Comparative Health Research Outcomes of NOvel Surgery in Prostate Cancer | 100 | Mar 2023 |



NCT: national clinical trial

^aDenotes industry-sponsored or cosponsored trial

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion 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 2022.⁴⁷ 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 is 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 (v.4.2026) recommend only cryosurgery, HIFU, or irreversible electroporation (IRE) as local therapy options for radiotherapy recurrence in the absence of metastatic disease (category 2B).⁶⁰ 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.⁵⁵

National Cancer Institute

The National Cancer Institute (NCI; 2024) updated its information on prostate cancer treatments.⁶¹ The NCI indicated that cryosurgery, 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 (NICE) published guidelines in 2023 recommending, "Evidence on the safety of focal therapy using high-intensity focused ultrasound for localised prostate cancer is adequate, but evidence on its efficacy is limited. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research."¹⁴

NICE also issued guidance (2019; updated in 2021) on management for localized prostate cancer.¹³ 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.

US Preventive Services Task Force Recommendations

The US Preventive Services Task Force published recommendations for prostate cancer screening.⁶²

Medicare National Coverage

There is no national coverage determination.



Regulatory Status

Focal Laser Ablation

In 2010, the Visualase Thermal Therapy System (Medtronic) and, in 2015, the TRANBERG CLS|Laser fiber (Clinical Laserthermia Systems) were cleared for marketing by the US 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 to a novel 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 US. 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

RFA devices have been cleared for marketing by the FDA through the 510(k) process for general use for soft tissue cutting, 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.

References

1. American Cancer Society. Key statistics for prostate cancer. May 30, 2025. <https://www.cancer.org/cancer/types/prostate-cancer/about/key-statistics.html>. Accessed December 31, 2025.
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 (updated 2021); <https://www.nice.org.uk/guidance/ng131/chapter/Recommendations>. Accessed December 31, 2025
14. National Institute for Health and Care Excellence (NICE). Focal Therapy Using High-Intensity Focused Ultrasound for Localized Prostate Cancer [IPG756]. 2023; <https://www.nice.org.uk/guidance/ipg756>. Accessed December 31, 2025.
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. Eylet 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-aea/astro-guideline-2022>. Accessed December 31, 2025.

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. American Urological Association (AUA). A Randomized Clinical Trial Comparing Focal Ablation And Radical Prostatectomy In Patients With Unilateral Clinically Significant Prostate Cancer. Intention To Treat Analysis At Two-Year Follow-Up (Pd39-06). Published May 2024. <https://www.auajournals.org/doi/10.1097/01.JU.0001008924.16121.42.06>. Accessed July 24, 2025.

52. 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

53. 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

54. 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

55. 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

56. Polverino P, Lo Re M, Moscardi L, et al. Transperineal Focal Laser Ablation of the Prostate for Prostate Cancer: A Systematic Review of the Literature. *Cancers (Basel)*. Mar 13 2025; 17(6). PMID 40149303

57. Tay KJ, Fong KY, Stabile A, et al. Established focal therapy-HIFU, IRE, or cryotherapy-where are we now?-a systematic review and meta-analysis. *Prostate Cancer Prostatic Dis*. Oct 28 2024. PMID 39468217

58. Wang CJ, Pang CC, Qin J, et al. Comparative study of HIFU partial gland ablation and robot-assisted radical prostatectomy for localized prostate cancer: an evidence-based approach. *J Robot Surg*. Oct 14 2024; 18(1): 367. PMID 39402287

59. Zhu A, Strasser MO, McClure TD, et al. Comparative Effectiveness of Partial Gland Cryoablation Versus Robotic Radical Prostatectomy for Cancer Control. *Eur Urol Focus*. Sep 2024; 10(5): 843-850. PMID 38677913

60. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: prostate cancer. Version 4.2026. https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed December 31, 2025.

61. National Cancer Institute. Prostate Cancer Treatment (PDQ) Patient Version: Treatment Option Overview. 2024. https://www.cancer.gov/types/prostate/patient/prostate-treatment-pdq#link/_142. Accessed December 31, 2025.



62. U.S. Preventive Services Task Force. Final Recommendation Statement: Prostate Cancer: Screening. 2018; <https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/prostate-cancer-screening1>. Accessed December 31, 2025.

History

| Date | Comments |
|----------|--|
| 07/14/15 | New Policy. Policy created with literature review through March 3, 2015. Use of any focal therapy modality is considered investigational for treatment of localized prostate cancer. |
| 11/10/15 | Annual Review. Policy updated with literature review through July 28, 2015; reference 55 added. Policy statement unchanged. |
| 11/01/16 | Annual Review, approved October 11, 2016. Policy updated with literature review through July 26, 2016; references 55-57 and 59-63 were added. Policy statement unchanged. |
| 08/01/17 | Interim review, approved July 11, 2017. Policy moved into new format. No changes to policy statement. |
| 11/01/17 | Annual Review, approved October 19, 2017. Policy updated with literature review through July 20, 2017; reference 16 added. Policy statement unchanged. |
| 12/01/18 | Annual Review, approved November 6, 2018. Policy updated with literature review through July 2018; reference 57 added; reference 61 updated; several references removed. Policy statement unchanged. Removed CPT code 53899, added CPT code 53854 (new code effective 1/1/19). |
| 05/10/19 | Minor edit, added note to clarify that this policy does not address Rezum System for Benign Prostatic Hyperplasia (BPH). |
| 09/01/19 | Minor edit, added 2.01.49 to Related Policies. |
| 12/01/19 | Annual Review, approved November 6, 2019. Policy updated with literature review through July 2019; reference on NCCN updated. Policy statement unchanged. |
| 01/01/20 | Coding update, added CPT code 0582T (new code effective 1/1/20). |
| 08/01/20 | Coding update. Removed CPT code 0582T. |
| 12/01/20 | Annual Review, approved November 3, 2020. Policy updated with literature review through August 2020; no references added. Policy statement unchanged. Removed CPT code 53854 and added CPT code 0582T. Added new CPT code 55880 effective 1/1/2021. |
| 07/01/21 | Coding update, Added CPT code 0655T. |



| Date | Comments |
|----------|--|
| 12/01/21 | Annual Review, approved November 2, 2021. Policy updated with literature review through July 28, 2021; references added. Policy statement unchanged. |
| 12/01/22 | Annual Review, approved November 7, 2022. Policy updated with literature review through August 2, 2022; references added. Minor editorial refinements to policy statements; intent unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization. |
| 01/01/23 | Coding update. Added new CPT codes 0738T and 0739T. |
| 12/01/23 | Annual Review, approved November 6, 2023. Policy updated with literature review through July 11, 2023; references added. Policy statement unchanged. |
| 12/01/24 | Annual Review, approved November 11, 2024. Policy updated with literature review through July 18, 2024; references added. Policy statement reformatted; however, policy intent unchanged. Added CPT codes 0600T and 0601T to match content update. |
| 07/01/25 | Coding update. Added new CPT code 0950T due to Q3 code updates. |
| 09/03/25 | Minor update made to related policy section. Added 2.01.544 Transurethral Water Vapor Thermal Therapy and Transurethral Water Jet Ablation for Benign Prostatic Hyperplasia. |
| 12/01/25 | Annual Review, approved November 10, 2025. Policy updated with literature review through July 22, 2025; references added. Policy statements unchanged. |
| 01/01/26 | Interim Review, approved December 9, 2025. Policy statement updated to remove irreversible electroporation (IRE) which is now addressed in policy 6.01.68 Irreversible Electroporation of Tumors Located in the Liver, Pancreas, Kidney, Lung, or Prostate. CPT codes 0600T and 0601T removed in alignment with this update. |
| 02/01/26 | New policy, 8.01.541 Focal Treatments for Prostate Cancer, replaces policy 8.01.61 Focal Treatments for Prostate Cancer, approved January 13, 2026. Policy renumbered due to removal of Nanoknife as method of irreversible electroporation (IRE) which is now included in policy 6.01.68 Irreversible Electroporation of Tumors Located in the Liver, Pancreas, Kidney, Lung, or Prostate. Policy statements unchanged. Literature review through December 31, 2025. No references added, references updated. |

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2026 Premera All Rights Reserved.

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benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

