

MEDICAL POLICY

POLICY TITLE	FOCAL TREATMENTS FOR PROSTATE CANCER (FORMERLY TREATMENTS OF THE PROSTATE (FOCAL, WATER VAPOR, AQUABLATION, AND HYDROGEL SPACER))
POLICY NUMBER	MP 4.043

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☐ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective date:	10/1/2026

POLICY

Use of any focal therapy modality to treat individuals with localized prostate cancer is **investigational**. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Policy Guidelines

There are no specific CPT codes for focal therapy using cryoablation, focal therapy using radiofrequency ablation, or focal therapy using photodynamic therapy. It is likely they are reported with CPT code 55899 unlisted procedure, male genital system.

Cross-References:

MP 1.147 Prostatic Urethral Lift

MP 1.164 Temporarily Implanted Nitinol Device (iTind) for Benign Prostatic Hyperplasia

MP 4.053 Transurethral Water Vapor Thermal Therapy and Transurethral Water Jet Ablation (Aquablation) for Benign Prostatic Hypertrophy

MP 4.054 Hydrogel Spacer Use During Radiotherapy for Prostate Cancer

MP 5.053 Magnetic Resonance–Guided Focused Ultrasound

PRODUCT VARIATIONS

This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: <https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies>.

DESCRIPTION/BACKGROUND

PROSTATE CANCER

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Prostate cancer is the second most common cancer diagnosed among men in the U.S. According to the American Cancer Society, nearly 333,830 new cases are estimated to be diagnosed in the U.S. in 2026, associated with around 36,320 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. The prostate cancer death rate declined by about half from 1993 to 2022, likely due to earlier detection and improved treatment.

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 evidence review does not cover focal brachytherapy.

Regulatory Status

Focal Laser Ablation

In 2010, the Visualase® Thermal Therapy System (Medtronic) and, in 2015, the TRANBERG® CLS|Laser fiber (Clinical Laserthermia Systems) were cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process to necrotize or coagulate soft tissue through interstitial irradiation or thermal therapy under 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

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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.

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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

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 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 (e.g., 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.

DEFINITIONS

N/A

DISCLAIMER

Capital Blue Cross' medical policies are used to determine coverage for specific medical technologies, procedures, equipment, and services. These medical policies do not constitute medical advice and are subject to change as permitted by law or applicable clinical evidence from independent treatment guidelines. Treating providers are solely responsible for medical advice and treatment of members. These policies are not a guarantee of coverage or payment. Payment of claims is subject to a determination regarding the member's benefit program and eligibility on the date of service, and a determination that the services are medically necessary and appropriate. Final processing of a claim is based upon the terms of contract that applies to the members' benefit program, including benefit limitations and

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exclusions. If a provider or a member has a question concerning this medical policy, please contact Capital Blue Cross' Provider Services or Member Services.

CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational when used to describe Focal Treatments for Prostate Cancer

Procedure Codes							
0582T	0601T	0655T	0739T	0941T	0942T	0943T	51721
55877	55880	55881	55882	55899*			

*Used for focal therapies that do not have their own procedure code

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POLICY HISTORY

MP 4.043	04/03/2020 Consensus Review. Policy Statement unchanged. ICD codes: N13.8; R33.8; R39.15; R39.16 added and updated. References reviewed and updated. Variations updated.
	07/16/2020 Minor Review. Policy Statement changed to include the Hydrogel Spacer. Variation Statement updated. References reviewed, updated and Hydrogel Spacer references added. Coding reviewed. New codes added: 55874; C61; C79.82; D07.5; D40.0; D49.59.
	11/18/2020 Administrative Update. Added code 55880. Effective 01/01/2021

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12/14/2020 Administrative Update. Deleted code C9747. Effective 01/01/2021.
03/10/2021 Administrative Update. Revised Code C9761. Effective 04/01/2021.
09/08/2021 Minor Review. Addition of aquablation as INV. Update to include titanium and stainless-steel allergy. Updated coding, references, background, and rationale.
06/24/2022 Administrative Update. C9761 removed.
12/02/2022 Minor Review. Aquablation moved to NMN. HIFU now NMN, Updated to Urethral Lift criteria. Updated INV list to include PAE and temporary urethral stents. Updates and clarification to multiple other criteria statements. References, background, rationale and coding updated.
11/22/2023 Consensus Review. Updated background and rationale. New references.
10/31/2024 Major Review. Policy statement changed from MN to INV for water vapor thermal therapy and hydrogel rectal spacer. Changed all policy language from not medically necessary to INV. Added codes 0600T, 0601T, and 0739T to investigational table. Moved codes 53854 and 55874 to investigational table. Updated background and references.
12/13/2024 Administrative Update. Added codes 0941T-0943T, 51721, 53865, 53866, 55881, 55882. Effective 01/01/2025.
06/25/2025 Minor Review. Title change; formerly Treatments of the Prostate. Prostatic Urethral Lift and Nitinol Device (along with associated procedure codes) were removed and placed into their own policies (MP 1.147 and MP 1.164. Updated cross references, background, rationale, coding table, and references.
09/10/2025 Administrative Update. Added New Code 0950T
12/11/2025 Administrative update. Deleted code 0421T was replaced with New Code 52597. 0600T was removed as it is a revised code and New Code 55877 will take its place. Eff date 01/01/2026
04/01/2026 Minor Review. Statements and procedure codes for BPH have been moved to MP 4.053. Statements and procedure codes for Hydrogel Spacer have been moved to MP 4.054. 0950T will be moved to MP 4.002 E/I.

Health care benefit programs issued or administered by Capital Blue Cross and/or its subsidiaries, Capital Advantage Insurance Company®, Capital Advantage Assurance Company®, and Keystone Health Plan® Central. Independent licensees of the Blue Cross BlueShield Association. Communications issued by Capital Blue Cross in its capacity as administrator of programs and provider relations for all companies.