MEDICAL POLICY

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Medical Policy Title	**Focal Therapies for Prostate Cancer Treatment**
Policy Number	**7.01.01**
Current Effective Date	August 21, 2025
Next Review Date	August 2026

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Cryosurgery and high-intensity focused ultrasound (HIFU) for recurrent prostate cancer is considered **medically appropriate** when **ALL** of the following criteria have been met:

   A. Recurrence of prostate cancer after radiation therapy (as evidence by positive, repeat biopsy);

   B. Absence of metastatic disease.

II. Cryotherapy or other focal therapies (i.e., HIFU) performed for routine primary therapy for localized prostate cancer are considered **investigational.**

III. The following focal therapies for the routine treatment of prostate cancer are considered **investigational**. These treatments include, but are not limited to, **ANY** of the following:

   A. Vascular-Targeted Photodynamic, therapy (VTP);

   B. Irreversible Electroporation (IRE);

   C. NanoKnife for tissue ablation;

   D. Laser Interstitial Thermal Therapy (LITT);

   E. Transurethral Ultrasound Ablation (TULSA);

   F. Magnetic field induction (NanoTherm therapy);

   G. High energy water vapor thermotherapy.

RELATED POLICIES

Corporate Medical Policy

6.01.16 Brachytherapy or Radioactive Seed Implantation for Prostate Cancer

8.01.06 Photodynamic Therapy for Malignant Disease

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

Not Applicable

DESCRIPTION

Cryosurgical Ablation

Cryosurgical ablation of the prostate is an alternative method of treatment for prostate cancer. The cryoablation technique involves the use of transrectal, ultrasound-guided, percutaneous placement of cryoprobes to freeze prostate tissue to produce well-demarcated areas of cell injury and destruction. Refinements in the technique, with transrectal ultrasonography, improved cryosurgical instrumentation, and the use of commercial urethral warmers have decreased the complications associated with the early attempts at cryosurgery. The benefits of cryosurgery of the prostate include a shorter surgical procedure time with minimal blood loss.

High Intensity Focused Ultrasound (HIFU)

HIFU is a noninvasive approach that uses precisely delivered ultrasound energy to achieve tumor cell necrosis without radiation or surgical excision. This technique is also referred to as ultrasonic ablation, sonablation or focal ultrasound surgery. HIFU involves the use of a transrectal probe to plan, perform, and monitor treatment in a real-time sequence to ablate the entire prostate gland or small discrete lesions. HIFU is a promising treatment for prostate cancer especially in patients with low and intermediate risk disease who chose to not undergo open surgery. HIFU is a minimally invasive, outpatient, radiation free procedure that patients can undergo then return home. This advancement in the treatment of prostate cancer is making it possible for patients with earlier stages of the disease to maintain their quality of life without open surgery. HIFU can also be used if disease recurs, despite what earlier treatment methods were deployed.

Vascular-Targeted Photodynamic Therapy (VTP) or Photodynamic Therapy (PDT)

VTP or PDT is a tissue-preserving treatment for low-risk prostate cancer which consists of intravenous 4 mg/kg padeliporfin over 10 min and optical fibers inserted into the prostate to cover the desired treatment zone and subsequent activation by laser light. For treating prostate cancer, the photosynthesizer TOOKAD soluble (WST11) is used. The technical term for this treatment is TOOKAD Soluble VTP therapy.

Irreversible Electroporation (IRE)

IRE is used as focal therapy to target areas of significant tumor burden to ablate tumors in situ or improve margins of resection. Primarily being used for pancreas, kidney, liver and prostate tumors. IRE destroys cancerous tumors with short electrical pulses without thermal heat disrupting permeabilization of cell membrane phospholipids. The NanoKnife System which became commercially available for research purposes in 2009 is being solely used for the surgical ablation of soft tissue tumors.

Laser Interstitial Thermotherapy (LITT)

LITT treatment produces focal thermal ablation leading to lesion cytoreduction through tissue coagulation, necrosis, and cellular apoptosis.

Trans-Urethral Ultrasound Ablation (TULSA)

TULSA is a transurethral prostate tissue ablation system that uses real-time MRI, robotically driven, directional thermal ultrasound and closed-loop temperature feedback control software. It provides incision- and radiation-free, whole or partial prostate gland ablation, protecting the urethra and rectum to preserve men's functional abilities.

Magnetic Field Induction (NanoTherm therapy)

The NanoTherm liquid containing the magnetic nanoparticles is specifically injected into the tumor or applied at the resection cavity wall in the course of the tumor resection.
The particles, which contain iron oxide, are then activated during six one-hour sessions in the NanoActivator by an externally applied, rapidly alternating magnetic field, which generates heat. This either destroys the tumor cells or sensitizes them to additional treatment approaches such as radiotherapy and/or chemotherapy (MagForce USA, Inc).

Transurethral Water Vapor Thermal Therapy

Transurethral water vapor thermal therapy is a transurethral needle ablation technique which injects radiofrequency-generated, sterile water vapor (~103 degrees C) into enlarged prostate tissue. As the steam encounters the prostatic tissue, it condenses back into water, releasing large amounts of thermal energy, disrupting the prostatic cell membranes and leading to cell death and necrosis. It takes approximately three months for the body to reabsorb dead tissue, decreasing prostate volume and relieving LUTS. The thermal energy is confined to the prostate, which reduces the risk of injury to other parts of the body. The procedure is performed under local anesthesia in an office or outpatient setting. Currently there is no literature or professional society that supports this therapy for prostate cancer.

SUPPORTIVE LITERATURE

HIFU

Maestroni et al (2021) conducted a systematic review that evaluated the safety and cancer control rates of high-intensity focused ultrasound (HIFU) following failure of External Beam Radiation Therapy (EBRT) for localized prostate cancer. The analysis of 1241 patients from predominantly retrospective studies. All patients underwent EBRT prior to HIFU for localized prostate cancer. The mean age was 68.6 years with a prostate specific antigen (PSA) value of 5.87 ng/mL before treatment. At the time of salvage HIFU, 38.3% patients were on androgen-deprivation therapy and 24.71% continued the therapy after the treatment. Follow-up was a mean follow-up of 24.3 months after salvage HIFU. The percentage of patients who had recurrence was 51.6% which was independent of the length of follow-up. The overall survival (OS) was 85.2% at five years and one study reported an OS of 72% at seven years. The authors concluded that salvage HIFU is effective in the treatment of radiorecurrent clinically localized prostate cancer. Limitations included analysis of predominantly retrospective studies, heterogeneity of data collected making it difficult to compare the results and the criterion for defining recurrence is not the same.

Ingrosso et al (2020) conducted a systematic review and meta-analysis that evaluated the role of nonsurgical salvage modalities in radiorecurrent prostate cancer and the associated clinical outcomes

with toxicity profiles. The meta-analysis included 64 case-series studies including 5585 patients. All patients underwent primary radiation therapy (RT) for localized prostate cancer. Clinical outcomes were measured using the Phoenix definition to determine biochemical control rates while toxicity was measured using the Common Terminology Criteria for Adverse Events (CTCAE) and Clavien-Dindo scales. Brachytherapy (BT) and cryotherapy (CRYO) were investigated in 22 studies, HIFU in 13 studies, and EBRT in seven studies. The median follow-up after salvage therapy was 31 months. Patients underwent different imaging modalities to assess local relapse including MRI and choline PET. Prostate biopsies were performed in 5546 patients, for which the median Gleason score was 7. Biochemical control rates were lowest for patients treated with HIFU and highest for patients treated with BT and EBRT. The lowest prevalence of incontinence was for patients treated with BT and the highest was among patients treated with HIFU. The authors concluded that nonsurgical therapeutic options, especially BT, showed good outcomes in terms of biochemical control and tolerability in the local recurrence setting. Limitations included high between-study heterogeneity potentially by the lack of prospective data and by the intrinsic bias for case series.

Irreversible Electroporation (IRE)

Faiella et al (2024) evaluated the most recent research from 2000 to 2023 to investigate the applications of IRE for prostate cancer, including the primary- and salvage-intent. Primary-intent IRE, in-field recurrence ranges from zero to 33%. Urinary continence after the treatment was greater than 86%. Preserved potency varied from 59-100%. Regarding complications, the highest occurrence rates are for those of Grades I and II (20–77% and 0–29%, respectively). Grade III complications represent less than 7%. Specific oncological outcomes, both PCa-specific survival and overall survival are 100%. Metastasis-free survival is 99.6%. In a long-term study, the Kaplan–Meier FFS rates reported are 91% at 3 years, 84% at 5 years, and 69% at 8 years. In the single study with salvage-intent IRE, the in-field recurrence was 7%. Urinary continence was still high (93%), but preserved potency was significantly lower than primary-intent IRE patients (23%). In addition, Grade III complications were slightly higher (10.8%). In conclusion, in males with localized low–intermediate-risk prostate cancer, IRE had an excellent safety profile and might have positive results for sexual and urinary function.

PROFESSIONAL GUIDELINE(S)

The American Urological Association (AUA) and American Society for Radiation Oncology (ASTRO) and endorsed by the Society of Urologic Oncology (SUO) released 2022 guidelines for clinically localized prostate cancer. The guidelines offer the following recommendations regarding focal therapies:

- 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)

The National Comprehensive Cancer Network (NCCN) guidelines for Prostate Cancer Version 2.2025

recommends:

- Cryosurgery and high-intensity focused ultrasound (HIFU) as local therapy options for RT recurrence in the absence of metastatic disease.
- 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 Institute for Health and Care Excellence (NICE) notes that current evidence on the safety and efficacy of IRE for treating prostate cancer is inadequate in quantity and quality.

REGULATORY STATUS

The TULSA procedure received FDA clearance August 16, 2019, to begin marketing for the ablation of prostate tissue.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I) =Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
55873	Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring)
55880	Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound (HIFU), including ultrasound guidance
55899	Unlisted procedure, male genital system
0582T (E/I)	Transurethral ablation of malignant prostate tissue by high-energy water vapor thermotherapy, including intraoperative imaging and needle guidance
0600T (E/I)	Ablation, irreversible electroporation; 1 or more tumors per organ, including imaging guidance, when performed, percutaneous
0601T (E/I)	Ablation, irreversible electroporation; 1 or more tumors, including Fluoroscopic and ultrasound guidance, when performed, open
0655T (E/I)	Transperineal focal laser ablation of malignant prostate tissue, including transrectal imaging guidance, with MR-fused images or other enhanced ultrasound imaging
0738T (E/I)	Treatment planning for magnetic field induction ablation of malignant prostate tissue, using data from previously performed magnetic resonance imaging (MRI) examination

Code	Description
0739T (E/I)	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

HCPCS Codes

Code	Description
C2618	Probe/needle, cryoablation

ICD10 Codes

Code	Description
C61	Malignant neoplasm of prostate
C79.82	Secondary malignant neoplasm of genital organs
D07.5	Carcinoma in situ of prostate
R97.21	Rising PSA following treatment for malignant neoplasm of prostate
Z85.46	Personal history of malignant neoplasm of prostate
Z92.3	Personal history of irradiation

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SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Cryosurgery of Prostate (NCD 230.9) [accessed 2025 May 22]

Salvage High-intensity Focused Ultrasound (HIFU)Treatment in Prostate Cancer is not addressed in National or Regional Medicare coverage determinations or policies.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION

Committee Approval Dates

09/16/99, 04/19/01, 11/15/01, 10/16/02, 08/21/03, 07/15/04, 07/21/05, 07/20/06, 07/19/07, 07/17/08, 07/16/09, 08/19/10, 08/18/11, 08/16/12, 08/15/13, 08/21/14, 08/20/15, 07/21/16, 07/20/17, 07/19/18, 07/18/19, 06/18/20, 04/15/21, 02/17/22, 02/16/23, 02/22/24, 08/22/24, 08/21/25

Date	Summary of Changes
08/21/25	• Annual review, policy intent unchanged.
01/01/25	• Summary of changes tracking implemented.
09/16/99	• Original effective date