MEDICAL POLICY

Medical Policy Details	
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Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), 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 STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, cryosurgery and high-intensity focused ultrasound (HIFU) for local therapy for recurrent (cancer that returns) prostate cancer after radiation therapy has been medically proven to be effective and, therefore, is considered a **medically appropriate** treatment option when **ALL** of the following criteria are met:

A. Life expectancy greater than five (5) years; **AND**
B. Low-Risk (Low risk is defined as PSA <10ng/ml **AND** Gleason Score less than 7 AND Clinical stage T1-T2a); **AND**
C. Positive biospy, recent (i.e. repeat), completed due to suspicion of local recurrence of prostate cancer; **AND**
D. Absence of metastatic disease.

II. Based upon our criteria and assessment of the peer-reviewed literature, salvage cryosurgery for recurrent prostate cancer is considered a **medically appropriate** treatment option for those patients who have recurrent localized disease and who have failed a trial of radiation therapy as a primary treatment with **ONE** of the following criteria:

A. Stage T2b or below; **OR**
B. Gleason score less than 9; **OR**
C. PSA less than 8 ng/ml.

III. Based upon our criteria and assessment of the peer-reviewed literature, salvage cryosurgery for recurrent prostate cancer after failure of any treatments other than radiation therapy as a primary therapy has not been medically proven to be effective and, therefore, is considered **investigational.**

IV. Based upon our criteria and assessment of the peer-reviewed literature, HIFU, as routine primary treatment for prostate cancer, has not been medically proven to be effective and, therefore, is considered **investigational.**

V. Based upon our criteria and assessment of the peer-reviewed literature, additional focal therapies for the treatment of prostate cancer (e.g.vascular-targeted photodynamic, therapy (VTP), irreversible electroporation (IRE), including use of Nano Knife for tissue ablation, laser interstitial thermal therapy, (LITT), transurethral ultrasound ablation (TULSA)), Magnetic Field induction (NanoTherm therapy), and other focal treatments, have not been medically proven to be effective as routine treatment for prostate cancer, and, therefore, considered **investigational**.

Refer to Corporate Medical Policy #6.01.16 Brachytherapy or Radioactive Seed Implantation for Prostate Cancer.

Refer to Corporate Medical Policy #8.01.06 Photodynamic Therapy for Malignant Disease

Refer to Corporate Medical Policy #11.01.03 Experimental and Investigational Services

DESCRIPTION

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 in order 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) 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, out patient, radiation free procedure that patients can undergo in a few hours 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.

Sonablate 450 (SonaCare Medical; Focus Surgery, Inc.) has obtained 510(K) Food and Drug Administration (FDA) clearance in the U.S. under a De Novo regulatory classification which is an evaluation of automatic class III designation. Sonablate 500, (SonaCare Medical; Focus Surgery, Inc.) is manufactured by SonaCare Medical, Inc. (Charlotte, NC) and Misonix, Inc. (Farmingdale, NY) and is approved by the FDA as an investigational device for clinical trials in the U.S. Sonatherm laparoscopic HIFU surgical ablation system (SonaCare Medical; Focus Surgery, Inc.) has obtained 510(K) clearance in the U.S. and has a CE (Conformité Européene or European Conformity) mark and regulatory authorization in more than 30 countries outside the U.S. Ablatherm Integrated Imaging HIFU device (EDAP Technomed, Inc., Austin, TX) was granted 510(k) marketing clearance by the FDA since it was determined to be substantially equivalent to the Sonablate device and is indicated for the ablation of prostate tissue.

Vascular-targeted photodynamic therapy (VTP) or photodynamic therapy (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 vascular-targeted photodynamic (VTP) therapy.

Irreversible electroporation (IRE) is a relatively new ablation technique that is being 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) treatment produces focal thermal ablation leading to lesion cytoreduction through tissue coagulation, necrosis, and cellular apoptosis.

T*rans-urethral ultrasound ablation (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).

RATIONALE

Published studies have demonstrated that patients with low-volume, localized, primary prostate cancer undergoing cryosurgery remain biochemically disease-free up to three years. Surgically related morbidities of cryosurgery of the prostate have compared favorably to those reported for radical prostatectomy and radiation therapy. The available data suggest that select patients with radioresistant cancer have benefited from the use of cryosurgery as a salvage therapy. To date, case studies indicate that, at least in the short-term, cryosurgery is better tolerated than open salvage surgery and can be considered a treatment option for men who would not be candidates for open surgery. Complication rates can be minimized with improvements in technique and instrumentation and the use of experienced cryosurgeons.

Patient relevant outcome data such as disease free- and metastasis free- survival are now becoming available in the United States as more studies are completed, therefore post-treatment prostate biopsy data and the adverse event profile of HIFU are more available. HIFU currently remains experimental and investigational for primary treatment for localized prostate cancer.

The National Comprehensive Cancer Network (NCCN) Version 1.2023 recommends only 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 longterm 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.

Based on an ECRI systematic review (2019), (ECRI is a designated Evidence-based Practice Center by the U.S. Agency for Healthcare Research and Quality and a federally certified Patient Safety Organization by the U.S. Department of Health and Human Services), the available evidence on laser interstitial thermal therapy (LITT) is inconclusive as a minimally invasive alternative treatment for the treatment of localized prostate cancer.

The TULSA procedure received FDA clearance August 16, 2019 to begin marketing for the ablation of prostate tissue. Treatment (primary or salvage therapy) of prostate cancer is considered investigational as its effectiveness has not been established.

The American Urological Association (AUA), in collaboration with the American Society for Radiation Oncology (ASTRO) and Society of Urologic Oncology (SUO), released a new, evidence-based clinical guideline for the appropriate management of localized prostate cancer in 2017. The guidelines offer the following recommendations:

1. Clinicians may consider whole gland cryosurgery in low- and intermediate-risk localized prostate cancer patients who are not suitable for either radical prostatectomy or radiotherapy due to comorbidities, yet have >10 year life expectancy. (Expert Opinion).

2. Clinicians should inform localized prostate cancer patients considering whole gland cryosurgery that cryosurgery has similar progression-free survival to non-dose escalated external beam radiation (also given with neoadjuvant hormonal therapy) in low- and intermediate-risk disease, but conclusive comparison of cancer mortality is lacking. (Conditional Recommendation; Evidence Level: Grade C).
3. Clinicians should inform localized prostate cancer patients considering cryosurgery that it is unclear whether or not concurrent ADT improves cancer control, though it can reduce prostate size to facilitate treatment. (Clinical Principle).
4. Clinicians should inform localized prostate cancer patients considering whole gland cryosurgery that erectile dysfunction is an expected outcome. (Clinical Principle).
5. Clinicians should inform localized prostate cancer patients considering whole gland cryosurgery about the adverse events of urinary incontinence, and irritative and obstructive urinary problems. (Strong Recommendation; Evidence Level: Grade B).
6. Defects from prior transurethral resection of the prostate are a relative contraindication for whole gland cryosurgery due to the increased risk of urethral sloughing. (Clinical Principle).
7. Clinicians should inform those localized prostate cancer patients considering focal therapy or HIFU that these treatment options lack robust evidence of efficacy. (Expert Opinion)
8. Clinicians should inform localized prostate cancer patients considering HIFU that even though HIFU is approved by the FDA for the destruction of prostate tissue, it is not approved explicitly for the treatment of prostate cancer. (Expert Opinion)
9. Clinicians should inform low-risk prostate cancer patients who are considering focal therapy or high intensity focused ultrasound (HIFU) that these interventions are not standard care options because comparative outcome evidence is lacking. (Expert Opinion)
10. Clinicians should advise localized prostate cancer patients considering HIFU that tumor location may influence oncologic outcome. Limiting apical treatment to minimize morbidity increases the risk of cancer persistence. (Moderate Recommendation; Evidence Level: Grade C)
11. As prostate cancer is often multifocal, clinicians should inform localized prostate cancer patients considering focal therapy that focal therapy may not be curative and that further treatment for prostate cancer may be necessary. (Expert Opinion)

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:

1. 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)
2. Clinicians should not recommend whole gland or focal ablation for patients with high-risk prostate cancer outside of a clinical trial. (Expert Opinion)

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*

- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

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 *(Effective 01/01/2023)*
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 *(Effective 01/01/2023)*

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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*Key Article

KEY WORDS

Cryoablation of the prostate, high intensity focused ultrasound, vascular-targeted photodynamic therapy, irreversible electroporation, laser interstitial thermotherapy, trans-urethral ultrasound ablation

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for Cryosurgery of the Prostate. Please refer to the following NCD website for Medicare Members:
https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=123

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