MEDICAL MUTUAL®

Medical Policy

Policy: 200802

SUBJECT: Cryoablation
- Hepatocellular Carcinoma
- Neuroendocrine Tumors
- Prostate Carcinoma
- Renal Cell Carcinoma
- Soft Tissue Sarcoma

Initial Effective Date: 09/23/2008

Annual Review Date: 07/12/2024

Last Revised Date: 07/12/2024

Prior approval is required for some or all procedure codes listed in this Corporate Medical Policy.

Definition: Cryoablation (cryosurgery, cryotherapy, cryosurgical ablation) utilizes freeze-thaw cycles to cause destruction of tumor cells. Freezing results in cell death by forming ice crystals that are directly cytotoxic and leads to cell dehydration and rupture. Thawing results in microvascular occlusion with cell hypoxia, producing indirect ischemic injury. Cryoablation involves rapid cooling using a liquid gas inserted via cryoprobe, which is most often a straight metallic shaft, into the target tissue. An ice ball forms along the cryoprobe shaft that enlarges over time. The ablation zone is planned to cover the entire tumor as well as a margin of at least 5 millimeters (mm) beyond the tumor borders, to achieve a tissue temperature of –20°C at all tumor margins, thereby avoiding residual or untreated tumor.

Medical Necessity:

I. **Hepatocellular carcinoma (HCC):** The Company considers cryoablation for HCC **(CPT Codes 47371 and 47381) medically necessary** and eligible for reimbursement providing the following medical criteria are met:

- Conventional surgical resection is contraindicated or medically inappropriate (e.g., presence of co – morbid conditions, inaccessible tumor location); or
- All tumors are amenable to ablation such that the tumors and a margin of normal tissue can be treated; and
- Tumors are in a location accessible for ablation; and
- Each lesion ≤ 5 cm.
- Oligometastases or ≤ 3 lesions

II. **Neuroendocrine tumors:** The Company considers cryoablation for neuroendocrine tumors **(CPT Code 47381 and 47383) medically necessary** and eligible for reimbursement providing that the following medical criteria are met:

- Unresectable neuroendocrine tumors metastatic to the liver; and
- Near-complete treatment of tumor burden can be achieved.

III. **Prostate carcinoma:** The Company considers cryoablation for prostate carcinoma **(CPT Code 55873) medically necessary** and eligible for reimbursement providing that ***at least one*** of the following medical criteria is met:

- Primary treatment of clinically localized prostate cancer stage T1-T3[†]; and
- Lymph node involvement is not detected on imaging studies; or
- Salvage cryosurgery for recurrent prostate cancer with localized disease following a failed trial of radiation as primary therapy and ***at least one*** of the following:

    1. Prostate-specific antigen (PSA) < 8 ng/ml; or
    2. Gleason score[††] < 9; or
    3. Disease stage T2b[†] or below.

IV. **Renal cell carcinoma:** The Company considers cryoablation for renal cell carcinoma **(CPT Codes 50250 and 50593) medically necessary** and eligible for reimbursement providing that ***all*** of the following medical criteria are met:

- Renal cell carcinoma documented histologically; and
- Lesion ≤ 7 cm (Stage T1); and
- No evidence of metastasis; and
- ***At least one*** of the following:

    1. Not a candidate for open or laparoscopic surgery; or
    2. Solitary kidney; or
    3. Chronic renal insufficiency and marginal renal function; or
    4. Maximal renal preservation is medically necessary.

V. **Soft Tissue Sarcoma:** The Company considers cryoablation for soft tissue sarcoma **(CPT Code 20983) medically necessary** and eligible for reimbursement providing that the following medical criterion is met:

- Soft tissue sarcoma of the extremities or trunk in symptomatic patients with disseminated metastases.

NOTE: Endometrial cryoablation is addressed in Corporate Medical Policy 200302: Endometrial Ablation**.**

[†]American Joint Committee on Cancer: Prostate Cancer Staging:

TX	Primary tumor cannot be assessed
T0	No evidence of primary tumor

T1	Clinically inapparent tumor neither palpable nor visible by imaging
T1a	Tumor incidental histologic finding in 5% or less of tissue resected
T1b	Tumor incidental histologic finding in more than 5% of tissue resected
T1c	Tumor identified by needle biopsy (e.g., because of elevated PSA)
T2	Tumor confined within prostate
T2a	Tumor involves one-half of one lobe or less
T2b	Tumor involves more than one-half of one lobe but not both lobes
T2c	Tumor involves both lobes
T3	Tumor extends through the prostate capsule
T3a	Extracapsular extension (unilateral or bilateral)
T3b	Tumor invades seminal vesicle(s).
T4	Tumor is fixed or invades adjacent structures other than seminal vesicles, such as external sphincter, rectum, bladder, levator muscles, and/or pelvic wall

†† The Gleason score is calculated based on the dominant histologic grades, from grade 1 (well-differentiated) to grade 5 (very poorly differentiated). The classical score is derived by adding the two most prevalent pattern grades, yielding a score ranging from 2 to 10.

Documentation Requirements:

The Company reserves the right to request additional documentation and to deny reimbursement when it has determined that the services performed were not medically necessary, investigational, and/or a pattern of practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results, and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

Prior approval is required for CPT Codes 20983, 50250, 50593.

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Sources of Information:

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Applicable Code(s):	
CPT:	**20983, 47371, 47381, 47383, 50250, 50593 and 55873**
HCPCS:	**N/A**
ICD10 Procedure Codes:	**N/A**