

MEDICAL POLICY

POLICY TITLE	CRYOABLATION OF TUMORS LOCATED IN THE KIDNEY, LUNG, BREAST, PANCREAS, OR BONE
POLICY NUMBER	MP 1.088

CLINICAL BENEFIT	<input checked="" type="checkbox"/> MINIMIZE SAFETY RISK OR CONCERN. <input type="checkbox"/> MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. <input type="checkbox"/> ASSURE APPROPRIATE LEVEL OF CARE. <input type="checkbox"/> ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. <input checked="" type="checkbox"/> ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. <input type="checkbox"/> ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	4/1/2024

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I. POLICY

Cryosurgical ablation may be considered **medically necessary** to treat localized renal cell carcinoma that is no more than four (4) cm in size when **EITHER** of the following criteria is met:

- Preservation of kidney function is necessary (i.e., the patient has one kidney or renal insufficiency defined by a glomerular filtration rate of <60 mL/min/m²) **AND** standard surgical approach (i.e., resection of renal tissue) is likely to worsen kidney function substantially; **OR**
- Patient is not considered a surgical candidate.

Cryosurgical ablation may be considered **medically necessary** to treat lung cancer when **EITHER** of the following criteria is met:

- The patient has early-stage non-small cell lung cancer and is a poor surgical candidate; **OR**
- The patient requires palliation for a central airway-obstructing lesion.

Cryosurgical ablation may be considered **medically necessary** to treat benign or malignant tumors of the bone when **ALL** the following criteria are met:

- For pain control in individuals with metastatic bone disease confirmed with imaging (e.g., CT, MRI); **AND**
- Individuals who have failed or are poor candidates for standard treatments such as radiation or opioids; **AND**
- Individuals for which surgery is not an option.

Cryosurgical ablation is considered **investigational** as a treatment of the following:

- Benign or malignant tumors of the breast

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- Benign or malignant tumors of the lung that do not meet the medically necessary criteria above.
- Benign or malignant tumors of the pancreas
- Renal cell carcinomas in patients who are surgical candidates,

There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with these procedures.

POLICY GUIDELINES

This policy is limited to treatment in adults (age 18 years and older) and does not address pediatric populations.

Individuals receiving cryosurgical ablation for benign or malignant tumors of the bone should have an estimated life expectancy sufficient to achieve benefit of the procedure.

The National Comprehensive Cancer Network (NCCN) is a nonprofit alliance of cancer centers throughout the United States. NCCN develops the Clinical Practice Guidelines in Oncology which are recommendations aimed to help health care professionals diagnose, treat and manage patients with cancer. Guidelines evolve continuously as new treatments and diagnostics emerge and may be used by Capital Blue Cross when determining medical necessity according to this policy.

Cross-references:

MP 1.055 Radiofrequency Ablation of Primary or Metastatic Liver Tumors.

MP 1.084 Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors

MP 1.121 Cryosurgical Ablation of Primary or Metastatic Liver Tumors

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. 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>.

III. DESCRIPTION/BACKGROUND

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Cryosurgical ablation (hereafter referred to as cryosurgery or cryoablation) involves freezing of target tissues; this is most often performed by inserting a coolant-carrying probe into the tumor. Cryosurgery may be performed as an open surgical technique or as a closed procedure under laparoscopic or ultrasound guidance.

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Renal Tumors

Localized kidney cancer is treated with radical nephrectomy or nephron-sparing surgery. Prognosis drops precipitously if the tumor extends outside the kidney capsule because chemotherapy is relatively ineffective against metastatic renal cell carcinoma.

Lung Tumors and Lung Metastases

Early-stage lung tumors are typically treated surgically. Patients with early-stage lung cancer who are not surgical candidates may be candidates for radiotherapy with curative intent. Cryoablation is being investigated in patients who are medically inoperable, with small primary lung cancers or lung metastases from extrapulmonary primaries. Patients with more advanced local disease or metastatic disease may undergo chemotherapy with radiation following resection. Treatment is rarely curative; rather, it seeks to retard tumor growth or palliate symptoms.

Breast Tumors

Early-stage primary breast cancers are treated surgically. The selection of lumpectomy, modified radical mastectomy, or another approach is balanced against the patient's desire for breast conservation, the need for tumor-free margins in resected tissue, and the patient's age, hormone receptor status, and other factors. Adjuvant radiotherapy decreases local recurrences, particularly for those who select lumpectomy. Adjuvant hormonal therapy and/or chemotherapy are added, depending on presence and number of involved nodes, hormone receptor status, and other factors. Treatment of metastatic disease includes surgery to remove the lesion and combination chemotherapy.

Fibroadenomas are common benign tumors of the breast that can present as a palpable mass or a mammographic abnormality. These benign tumors are frequently surgically excised to rule out a malignancy.

Pancreatic Cancer

Pancreatic cancer is a relatively rare solid tumor that occurs almost exclusively in adults, and it is largely considered incurable. Surgical resection of tumors contained entirely within the pancreas is currently the only potentially curative treatment. However, the nature of the cancer is such that few tumors are found at such an early and potentially curable stage. Patients with more advanced local disease or metastatic disease may undergo chemotherapy with radiation following resection. Treatment is focused on slowing tumor growth and palliation of symptoms.

Bone Cancer and Bone Metastases

Primary bone cancers are extremely rare, accounting for less than 0.2% of all cancers. Bone metastases are more common, with clinical complications including debilitating bone pain.

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Treatment for bone metastases is performed to relieve local bone pain, provide stabilization, and prevent impending fracture or spinal cord compression.

Regulatory Status

Several cryoablation devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process for use in open, minimally invasive, or endoscopic surgical procedures in the areas of general surgery, urology, gynecology, oncology, neurology, dermatology, proctology, thoracic surgery, and ear, nose, and throat. Examples include:

- Cryocare® Surgical System (Endocare);
- CryoGen Cryosurgical System (Cryosurgical);
- CryoHit® (Galil Medical) for the treatment of breast fibroadenoma;
- IceSense3™, ProSense™, and MultiSense Systems (IceCure Medical);
- SeedNet™ System (Galil Medical); and
- Visica® System (Sanarus Medical).

Food and Drug Administration product code: GEH.

IV. RATIONALE

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Summary of Evidence

For individuals with early stage kidney cancer who are surgical candidates treated with cryoablation, the evidence includes comparative observational studies and systematic reviews. Relevant outcomes are overall survival (OS), disease-specific survival, quality of life, and treatment-related morbidity. Multiple comparative observational studies and systematic reviews of these studies have compared cryoablation to partial nephrectomy for early stage renal cancer. These studies have consistently found that partial nephrectomy is associated with better oncological outcomes than cryosurgery, but cryosurgery was associated with better perioperative outcomes, lower incidence of complications, and less decline in kidney function. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with early stage kidney cancer who are not surgical candidates and who are treated with cryoablation, the evidence includes comparative observational studies of cryoablation compared to partial nephrectomy or other ablative techniques, systematic reviews of these studies, and case series. Relevant outcomes are OS, disease-specific survival, quality of life, and treatment-related morbidity. Although oncological outcomes were better with surgery, in comparative observational studies, cryoablation was associated with less decline in kidney function. Recent case series totaling more than 400 patients showed cryoablation was associated with good oncological outcomes and preservation of renal function. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

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For individuals with non-small cell lung cancer (NSCLC) who are not surgical candidates, the evidence includes uncontrolled observational studies and case series. Relevant outcomes are OS, disease-specific survival, quality of life, and treatment-related morbidity. Medically inoperable patients with early stage primary lung tumors were treated with cryoablation in a consecutive series of 45 patients. Five year survival was 68%; the main complications were hemoptysis in 40% of patients and pneumothorax in 51%. A prospective single arm Phase 2 study of 128 patients reported on cryoablation for treatment of metastases to the lung. Cryoablation for metastatic lung cancer was studied in a single arm trial in 40 patients. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with NSCLC who require palliation for a central airway obstructing lesion who are treated with cryoablation, the evidence includes case series. Relevant outcomes are OS, disease-specific survival, quality of life, and treatment-related morbidity. There are no comparative studies. A series of 521 consecutive patients reported improvement in symptoms in 86% of patients, but multiple study design, conduct, and relevance limitations preclude drawing conclusions about efficacy or safety of cryoablation in this population. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with benign or malignant tumors of the bone who are treated with cryoablation, the evidence includes uncontrolled observational studies and case series. Relevant outcomes are OS, disease-specific survival, quality of life, and treatment-related morbidity. There is a small amount of literature on cryoablation for bone cancer and bone metastases. For bone metastases, the evidence base consists of 2 single arm nonrandomized studies (N = 61 and 66) and is inadequate to determine efficacy. Studies were limited by a lack of a comparator, potential for selection bias, and lack of blinding combined with subjective outcome measures. NCCN (Version 2.2023) states that ablation techniques should be considered for local bone pain, although specific therapies are outside the scope of the guideline.

For individuals with solid tumors located in the breast or pancreas who are treated with cryoablation, the evidence includes uncontrolled observational studies and case series. Relevant outcomes are OS, disease-specific survival, quality of life, and treatment-related morbidity. Due to the lack of prospective controlled trials, it is not possible to conclude that cryoablation improves outcomes for any indication better than alternative treatments. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

V. DEFINITIONS

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NA

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the

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applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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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.

Cryosurgical ablation is considered investigational for treatment of benign or malignant tumors of the breast, lung (other than defined above as medically necessary), or pancreas, and other solid tumors or metastases outside the liver and prostate and to treat renal cell carcinomas in patients who are surgical candidates.

Procedure Codes								
0581T	19105							

Cryosurgical ablation is considered medically necessary to treat localized renal cell carcinoma, lung and bone cancer when criteria is met:

Procedure Codes								
32994	50250	50542	50593	20983	C2618			

ICD-10-CM Diagnosis Codes	Description
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung

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ICD-10-CM Diagnosis Codes	Description
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
C40.00	Malignant neoplasm of scapula and long bones of unspecified upper limb
C40.01	Malignant neoplasm of scapula and long bones of right upper limb
C40.02	Malignant neoplasm of scapula and long bones of left upper limb
C40.10	Malignant neoplasm of short bones of unspecified upper limb
C40.11	Malignant neoplasm of short bones of right upper limb
C40.12	Malignant neoplasm of short bones of left upper limb
C40.20	Malignant neoplasm of long bones of unspecified lower limb
C40.21	Malignant neoplasm of long bones of right lower limb
C40.22	Malignant neoplasm of long bones of left lower limb
C40.30	Malignant neoplasm of short bones of unspecified lower limb
C40.31	Malignant neoplasm of short bones of right lower limb
C40.32	Malignant neoplasm of short bones of left lower limb
C40.80	Malignant neoplasm of overlapping sites of bone and articular cartilage of unspecified limb
C40.81	Malignant neoplasm of overlapping sites of bone and articular cartilage of right limb
C40.82	Malignant neoplasm of overlapping sites of bone and articular cartilage of left limb
C40.90	Malignant neoplasm of unspecified bones and articular cartilage of unspecified limb
C40.91	Malignant neoplasm of unspecified bones and articular cartilage of right limb
C40.92	Malignant neoplasm of unspecified bones and articular cartilage of left limb
C41.0	Malignant neoplasm of bones of skull and face
C41.1	Malignant neoplasm of mandible
C41.2	Malignant neoplasm of vertebral column
C41.3	Malignant neoplasm of ribs, sternum and clavicle
C41.4	Malignant neoplasm of pelvic bones, sacrum and coccyx

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ICD-10-CM Diagnosis Codes	Description
C41.9	Malignant neoplasm of bone and articular cartilage, unspecified
C64.1	Malignant neoplasm of right kidney, except renal pelvis
C64.2	Malignant neoplasm of left kidney, except renal pelvis
C64.9	Malignant neoplasm of unspecified kidney, except renal pelvis
C65.1	Malignant neoplasm of right renal pelvis
C65.2	Malignant neoplasm of left renal pelvis
C65.9	Malignant neoplasm of unspecified renal pelvis
C76.3	Malignant neoplasm of pelvis
C79.51	Secondary malignant neoplasm of bone
C79.52	Secondary malignant neoplasm of bone marrow
D16.00	Benign neoplasm of scapula and long bones of unspecified upper limb
D16.01	Benign neoplasm of scapula and long bones of right upper limb
D16.02	Benign neoplasm of scapula and long bones of left upper limb
D16.10	Benign neoplasm of short bones of unspecified upper limb
D16.11	Benign neoplasm of short bones of right upper limb
D16.12	Benign neoplasm of short bones of left upper limb
D16.20	Benign neoplasm of long bones of unspecified lower limb
D16.21	Benign neoplasm of long bones of right lower limb
D16.22	Benign neoplasm of long bones of left lower limb
D16.30	Benign neoplasm of short bones of unspecified lower limb
D16.31	Benign neoplasm of short bones of right lower limb
D16.32	Benign neoplasm of short bones of left lower limb
D16.4	Benign neoplasm of bones of skull and face
D16.5	Benign neoplasm of lower jaw bone
D16.6	Benign neoplasm of vertebral column
D16.7	Benign neoplasm of ribs, sternum, and clavicle
D16.8	Benign neoplasm of pelvic bones, sacrum and coccyx
D16.9	Benign neoplasm of bone and articular cartilage, unspecified

IX. REFERENCES

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49. Kurup A, Calistrom M. Image-guided ablation of skeletal metastases. In: *UpToDate Online Journal [serial online]*. Waltham, MA: UpToDate; updated January 2023
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X. POLICY HISTORY

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MP 1.088	CAC 3/30/10 Removed information regarding Barrett’s esophagus. Added cross-reference to MP-1.118, Treatment of Barrett’s Esophagus
	CAC 7/26/11 Adopt BCBSA.
	CAC 8/28/12 Consensus review. References updated; no change to policy statements. FEP variation added.
	CAC 10/30/12 Minor review. Lung cancer added to investigational policy statement. 10/16/12 code review
	CAC 11/26/13 Consensus review. References updated. Added Rationale section. Added the word “metastases” to investigational policy statement “Other solid tumors or <i>metastasis</i> outside the liver and prostate”.
	CAC 11/25/14 Consensus review. No changes to the policy statements. References and rationale updated. ICD-9 Surgical codes added to this policy. No other changes.
	Admin 5/28/15 Administrative correction only. No policy statement changes.
	CAC 11/24/15 Consensus. No change to policy statements. References and rationale updated. Coding updated.
	CAC 11/29/16 Consensus. No change to policy statements. References and rationale updated. Coding reviewed/updated. Product variation section reformatted.
	1/1/18 Administrative update. New code 32994 added plus end dated code 0340T removed; effective 1/1/18.
1/3/18 Minor review. Added medically necessary policy statements for treatment of lung cancer. Treatment of bone tumors added as investigational. Updated background, rationale and references. Coding Reviewed.	

MEDICAL POLICY

POLICY TITLE	CRYOABLATION OF TUMORS LOCATED IN THE KIDNEY, LUNG, BREAST, PANCREAS, OR BONE
POLICY NUMBER	MP 1.088

	11/30/18 Consensus review. No change to policy statements. Background and references updates. Rationale condensed.
	10/1/19 Administrative update. Added C64.9 and C65.9 to diagnosis list.
	10/1/19 Consensus. No change to policy statements. Background, summary of evidence and references updated.
	1/1/20 Coding update. Added new code 0581T.
	8/19/2020 Consensus Review. No change to policy statement; Coding reviewed with no changes; References reviewed and updated. Product Variation Statement updated.
	11/19/2021 Minor review. Title changed to Cryoablation of Tumors Located in the Kidney, Lung, Breast, Pancreas, or Bone to match BCBSA's change. Removed "Other solid tumors or metastasis outside the liver and prostate" criteria from investigational section. Added statement that policy not applicable to pediatric population. FEP language updated. NCCN language added. Background, Rationale and References updated.
	11/10/2022 Consensus review. No change to policy statement. Product variation language updated. Background and References updated.
	09/27/2023 Minor review. Cryoablation for benign and malignant tumors of the bone changed from investigational to medically necessary with criteria. Policy Guidelines section added. Added ICD10 codes C40.00, C40.01, C40.02, C40.10, C40.11, C40.12, C40.20, C40.21, C40.22, C40.30, C40.31, C40.32, C40.80, C40.81, C40.82, C40.90, C40.91, C40.92, C41.0, C41.1, C41.2, C41.3, C41.4, C41.9, C76.3, C79.51, C79.52, D16.00, D16.01, D16.02, D16.10, D16.11, D16.12, D16.20, D16.21, D16.22, D16.30, D16.31, D16.32, D16.4, D16.5, D16.6, D16.7, D16.8, D16.9. Rationale updated. References added.

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