

MEDICAL POLICY

POLICY TITLE	CRYOSURGICAL ABLATION OF MISCELLANEOUS SOLID TUMORS OTHER THAN LIVER, PROSTATE, OR DERMATOLOGIC TUMORS
POLICY NUMBER	MP-1.088

Original Issue Date (Created):	8/18/2003
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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 [GFR] of less than 60 mL/min per m²) and standard surgical approach (i.e., resection of renal tissue) is likely to substantially worsen kidney function; **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 is considered **investigational** as a treatment of the following:

- Benign or malignant tumors of the breast
- Benign or malignant tumors of the lung that do not meet the medically necessary criteria above.
- Benign or malignant tumors of the pancreas
- Benign or malignant tumors of the bone
- Renal cell carcinomas in patients who are surgical candidates,
- Other solid tumors or metastasis outside the liver and prostate

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

Cross-references:

MP-1.055 Radiofrequency Ablation of Primary or Metastatic Liver Tumors.

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MP-1.084 Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors
MP-1.118 Endoscopic Radiofrequency Ablation or Cryoablation for Barrett’s Esophagus
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 BlueCross. Please see additional information below, and subject to benefit variations as discussed in Section VI below.

FEP PPO - Refer to FEP Medical Policy Manual MP-7.01.92, Cryosurgical Ablation of Miscellaneous Solid Tumors Other than Liver, Prostate, or Dermatologic Tumors.

The FEP Medical Policy Manual can be found at:

[https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.](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 [CRA]) 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.

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.

Lung Tumors

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

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lung cancers or lung metastases. 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.

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.

Renal Cell Carcinoma

Localized renal cell carcinoma 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.

Cryosurgical Treatment

Cryosurgical treatment of various tumors including malignant and benign breast disease, lung cancer, pancreatic cancer, and renal cell carcinoma has been reported in the literature.

Regulatory Status

Several cryoablation devices have been cleared for marketing by the U.S. Food and Drug Administration 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;
- 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 who have solid tumors (located in areas of the breast, lung, pancreas, kidney, or bone) who receive cryosurgical ablation, the evidence includes nonrandomized comparative studies, case series, and systematic reviews of these nonrandomized studies. Relevant outcomes are overall survival, disease-specific survival, quality of life, and treatment-related morbidity. There is a lack of randomized controlled trials and high-quality comparative studies to determine

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the efficacy and comparative effectiveness of cryoablation. The largest amount of evidence assesses renal cell carcinoma in select patients (i.e., those with small tumors who are not surgical candidates, or those who have baseline renal insufficiency of such severity that standard surgical procedures would impair their kidney function). Cryoablation results in short-term tumor control and less morbidity than surgical resection, but long-term outcomes may be inferior to surgery. For other indications, there is less evidence, with single-arm series reporting high rates of local control. Due to the lack of prospective controlled trials, it is difficult to conclude that cryoablation improves outcomes for any indication better than alternative treatments. The evidence is insufficient to determine the effects of the technology on health outcomes.

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 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 BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross'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 BlueCross' Provider Services or Member Services. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

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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), pancreas, or bone and other solid tumors or metastases outside the liver and prostate and to treat renal cell carcinomas in patients who are surgical candidates.

CPT Codes®							
0581T	19105	20983					

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

CPT Codes®							
32994	50250	50542	50593				

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HCPCS Code	Description
C2618	Probe/needle, cryoablation

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
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
C64.1	Malignant neoplasm of right kidney, except renal pelvis

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ICD-10-CM Diagnosis Codes	Description
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

IX. REFERENCES

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X. POLICY HISTORY

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MP 1.088	CAC 3/25/03
	CAC 10/26/04
	CAC 10/25/05
	CAC 10/31/06
	CAC 2/27/07
	CAC 11/27/07
	CAC 11/25/08
	CAC 5/26/09
	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.	

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	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.
	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.

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