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MEDICAL POLICY – 7.01.92

Cryoablation of Tumors Located in the Kidney, Lung, Breast, Pancreas, or Bone

BCBSA Ref. Policy:	7.01.92
Effective Date:	Oct. 1, 2024
Last Revised:	Sept. 9, 2024
Replaces:	7.01.526

RELATED MEDICAL POLICIES:

7.01.95 Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors

Select a hyperlink below to be directed to that section.

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Introduction

Cryosurgical ablation uses extreme cold to destroy certain types of tumors. A probe is inserted into the tumor and an extremely cold liquid is circulated through the probe. An icy ball forms around the probe to freeze part or all of the tumor. The probe can be positioned in such a way as to maximize harm to the tumor while sparing nearby health tissue. The frozen area thaws, allowing the body to absorb the treated tissue. The policy discusses when this technique is considered medically necessary for specific breast and kidney tumors. It's also been tried for other kinds of tumors. Because larger and longer medical studies are needed, this technique is considered investigational (unproven) for other types of tumors.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Service	Medical Necessity
Cryosurgical ablation, localized renal cell carcinoma	**Cryosurgical ablation may be considered medically necessary to treat localized renal cell carcinoma that is no more than 4 cm in size when either of the following criteria is met:** • Preservation of kidney function is necessary (i.e., the individual has one kidney or renal insufficiency defined by a glomerular filtration rate [GFR] of < 60 mL/min per m^2) and standard surgical approach (i.e., resection of renal tissue) is likely to worsen kidney function substantially **OR** • Individual is not considered a surgical candidate
Cryosurgical ablation, lung cancer	**Cryosurgical ablation may be considered medically necessary to treat lung cancer when either of the following criteria is met:** • The individual has early-stage non-small cell lung cancer and is a poor surgical candidate **OR** • The individual requires palliation for a central airway obstructing lesion.

Service	Investigational
Cryosurgical ablation, malignant tumors	**Cryosurgical ablation is considered investigational to treat individuals with ANY of the following:** • Bone cancer and bone metastases • Lung tumors and lung metastases (other than defined above) • Malignant or benign tumors of the breast • Pancreatic cancers • Renal cell carcinomas in individuals who are surgical candidates

Documentation Requirements

The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:
• For cryosurgical ablation of localized renal cell carcinoma, documentation of:
  ○ The need to preserve the kidney because:
  ▪ Individual has one kidney
  OR

Documentation Requirements

- Individual has renal insufficiency as defined by a glomerular filtration rate (GFR) of < or equal to 60 mL/min/m^2, and standard surgical approach (i.e., resection of renal tissue) is likely to substantially worsen kidney function

OR

- Individual is considered not a surgical candidate

- For lung cancer, documentation of:
  - Individual has early-stage non-small cell lung cancer and is a poor surgical candidate

  OR

  - The individual requires palliation for a central airway obstructing lesion

Coding

Code	Description
CPT	
0581T	Ablation, malignant breast tumor(s), percutaneous, cryotherapy, including imaging guidance when performed, unilateral
19105	Ablation, cryosurgical, of fibroadenoma, including ultrasound guidance, each fibroadenoma
20983	Ablation therapy for reduction or eradication of 1 or more bone tumors (e.g., metastasis) including adjacent soft tissue when involved by tumor extension, percutaneous, including imaging guidance when performed; cryoablation
32994	Ablation therapy for reduction or eradication of 1 or more pulmonary tumor(s) including pleura or chest wall when involved by tumor extension, percutaneous, including imaging guidance when performed, unilateral; cryoablation
50250	Ablation, open, one or more renal mass lesion(s), cryosurgical, including intraoperative ultrasound guidance and monitoring, if performed
50593	Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy

Related Information

This policy does not address pediatric indications.

Evidence Review

Description

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.

Background

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. Individuals with early-stage lung cancer who are not surgical candidates may be candidates for radiotherapy with curative intent. Cryoablation is being investigated in individuals who are medically inoperable, with small primary lung cancers or lung metastases from extrapulmonary primaries. Individuals 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. Individuals with a more advanced local disease or metastatic disease may undergo chemotherapy with radiation following resection. Treatment focuses 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. Treatment for bone metastases is performed to relieve local bone pain, provide stabilization, and prevent impending fracture or spinal cord compression.

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 individuals 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.

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 in with early-stage primary lung tumors were treated with cryoablation in a consecutive series of 45 individuals. Five-year survival was 68%; the main complications were hemoptysis in 40% of individuals and pneumothorax in 51%. A prospective single arm Phase 2 study of 128 individuals reported on cryoablation for treatment of metastases to the lung. Cryoablation for metastatic lung cancer was studied in a single arm trial in 40 individuals. The evidence is insufficient 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 individuals reported improvement in symptoms in 86% of individuals, but multiple study design, conduct, and relevance limitations preclude drawing conclusions about efficacy or safety of cryoablation in this population. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with solid tumors located in the breast, pancreas or bone who are treated with cryoablation the evidence includes uncontrolled observational studies and case series. The 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.

Ongoing and Unpublished Clinical Trials

Some currently ongoing trials that might influence this review are listed in **Table 1**.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
Renal cancer			
NCT02399124[a]	ICESECRET PROSENSE Cryotherapy for Renal Cell Carcinoma Trial	120	Feb 2026
NCT04506671	A Prospective, Non-randomized, in Parallel Groups Study Evaluating the Efficacy and Safety of Percutaneous Cryoablation and Partial Nephrectomy in Localized T1b Renal Tumor	142	Jun 2025
Breast cancer			
NCT05505643	COOL-IT: Cryoablation vs Lumpectomy in T1 Breast Cancers: A Randomized Controlled Trial With Safety Lead-in	256	Oct 2031
NCT04334785	Evaluation for the Effectiveness and Safety of Cryo-ablation in the Treatment of Early Invasive Breast Cancer	186	May 2025
Bone cancer			
NCT05615545	Safety and Efficacy of Cryoablation in the Treatment of Advanced Bone and Soft Tissue Tumors: a Single-center Retrospective Study	30	Oct 2024

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

Clinical Input from Physician Specialty Societies and Academic Medical Centers

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2017 Input

Clinical input was sought to help determine whether the use of cryoablation for individuals with non-small cell lung cancer (NSCLC) who are either poor surgical candidates or who required palliation for a lesion obstructing the central airway would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, clinical input was received from nine respondents, including two specialty society-level responses, three physician-level responses identified by specialty societies, and four physicians identified by one health system.

For individuals with NSCLC who are either poor surgical candidates or who required palliation for a lesion obstructing the central airway who receive cryoablation, clinical input supports this use provides a clinically meaningful improvement in net health outcome and indicates this use is consistent with generally accepted medical practice.

2009 Input

In response to requests, input was received from two physician specialty societies (five reviews) and from two academic medical centers (three reviews) while this policy was under review in 2009. There was strong support for the use of cryoablation in the treatment of select individuals with renal tumors. There also was support for its use in the treatment of benign breast disease.

Reviewers generally agreed cryoablation was investigational in the treatment of pancreatic cancer.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or the National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Radiology

The American College of Radiology Appropriateness Criteria (2009, updated 2021) for post-treatment follow-up and active surveillance of renal cell carcinoma [RCC] indicated that, "Ablative therapies, such as radiofrequency ablation, microwave ablation, and cryoablation, have been shown to be an effective and safe alternative [to surgical resection] for the treatment of small, localized RCC."[43,44] These recommendations are based on a review of the data and expert consensus.

American Urological Association (AUA)

The American Urological Association (2021) updated its guidelines on evaluation and management of clinically localized sporadic renal masses suspicious for rRCC.[45] The guideline statements on thermal ablation (radiofrequency ablation, cryoablation) are listed in **Table 2**.

Table 2. Guidelines on Localized Masses Suspicious for Renal Cell Carcinoma

Recommendations	LOR	LOE
Guideline statement 25		
Clinicians should consider thermal ablation (TA) as an alternate approach for the management of cT1a renal masses <3 cm in size. For individuals who elect TA, a	Moderate	C

Recommendations	LOR	LOE
percutaneous technique is preferred over a surgical approach whenever feasible to minimize morbidity.		
Guideline statement 26		
Both radiofrequency ablation (RFA) and cryoablation may be offered as options for individuals who elect thermal ablation.	Conditional	C
Guideline statement 28		
Counseling about thermal ablation should include information regarding an increased likelihood of tumor persistence or local recurrence after primary thermal ablation relative to surgical extirpation, which may be addressed with repeat ablation if further intervention is elected	Strong	B

LOE: level of evidence; LOR: level of recommendation.

National Comprehensive Cancer Network

Kidney Cancer

The National Comprehensive Cancer Network (NCCN) (v.4.2024) guidelines on kidney cancer state that "thermal ablation (cryosurgery, radiofrequency ablation) is an option for the management of individuals with clinical stage T1 renal lesions. Thermal ablation is an option for clinical T1b masses in select individuals not eligible for surgery. Biopsy of lesions is recommended to be done prior to or at time of ablation. Ablative techniques may require multiple treatments to achieve the same local oncologic outcomes as conventional surgery."

The NCCN guidelines also note that "ablative techniques such as cryotherapy, microwave ablation, or radiofrequency ablation are alternative strategies for selected individuals, particularly for those who are older, those with competing health risks, and those with T1b masses not eligible for surgery." Additionally, the guidelines note that "randomized phase III comparison of ablative techniques with surgical resection (i.e., radical or partial nephrectomy by open or laparoscopic techniques) has not been performed." [46]

Non-Small Cell Lung Cancer

The NCCN (v.5.2024) guidelines for NSCLC made the following relevant recommendations:[47]

- Resection is the preferred local treatment modality for medically operable disease.

- Image-guided thermal ablation (IGTA) techniques include radiofrequency ablation, microwave ablation, and cryoablation.
- IGTA may be an option for select individuals not receiving stereotactic ablative radiotherapy or definitive radiotherapy.
- IGTA may be considered for those individuals who are deemed "high risk"- those with tumors that are for the most part surgically resectable but rendered medically inoperable due to comorbidities. In cases where IGTA is considered for high-risk or borderline operable individuals, a multidisciplinary evaluation is recommended.
- IGTA is an option for the management of NSCLC lesions <3 cm. Ablation for NSCLC lesions >3 cm may be associated with higher rates of local recurrence and complications.
- The guidelines do not separate out recommendations by ablation technique and note that "each energy modality has advantages and disadvantages. Determination of energy modality to be used for ablation should take into consideration the size and location of the target tumor, risk of complication, as well as local expertise and/or operator familiarity."

Cancer Pain

The NCCN Guidelines on Adult Cancer Pain (v.2.2024) do not address cryoablation specifically for pain due to bone metastases, but note that "ablation techniques may...be helpful for pain management in individuals who receive inadequate relief from pharmacological therapy."[48]

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

Several cryoablation devices have been cleared for marketing by the US 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)
- Visica System (Sanarus Medical)

FDA product code: GEH

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48. National Comprehensive Cancer Network. Adult Cancer Pain. Version 2.2024. **https://www.nccn.org/professionals/physician_gls/pdf/pain.pdf**. Accessed August 15, 2024.

History

Date	Comments
10/01/19	New policy, approved September 10, 2019, effective January 3, 2020. This policy was previously deleted but is now being reinstated to align with the BCBSA reference policy. This policy replaces 7.01.526 (originally effective 2004). Policy created with literature review through May 2019; references added and updated. Policy statement cryosurgical ablation for benign breast fibroadenomas changed from medically necessary to investigational.
01/01/20	Coding update, added CPT code 0581T (new code effective 1/1/20).
07/02/20	Coding update. Removed CPT code 19105.
07/14/20	Coding update. CPT code 50542 was removed from this policy. This applies to other criteria.
10/01/20	Annual Review, approved September 1, 2020. Policy updated with literature review through May 30, 2020; references added. Policy statements unchanged. Removed CPT codes 20983 and 0581T.
03/01/21	Coding update. Added CPT code 20983.
10/01/21	Annual Review, approved September 2, 2021. Policy updated with literature review through June 1, 2021. Title changed to "Cryoablation of Tumors Located in the Kidney, Lung, Breast, Pancreas, or Bone." Policy statement revised to align with separation of indications by tumor location - intent unchanged. Added CPT codes 0581T and 19105.
10/01/22	Annual Review, approved September 12, 2022. Policy updated with literature review through June 12, 2022; no references added. Terminology in policy statements changed from "patients" to "individuals" for standardization; intent unchanged. Clarifying edits made to investigational section of the policy.
10/01/23	Annual Review, approved September 11, 2023. Policy updated with literature review through June 6, 2023; references added. Policy statements unchanged.
10/01/24	Annual Review, approved September 9, 2024. Policy updated with literature review through June 3, 2024; no references added, guidelines updated. Policy statements unchanged.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.