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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, 2026
Last Revised:	Sep. 7, 2026
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 healthy 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

This policy does not address pediatric indications.

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 less than 60 mL/min/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 for benign or malignant tumors of the breast	**Cryosurgical ablation for benign or malignant tumors of the breast is considered investigational**
Cryosurgical ablation for lung, pancreas, or bone	**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) • 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

    - Individual has renal insufficiency as defined by a glomerular filtration rate (GFR) of < or 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

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

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 a 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 individual's desire for breast conservation, the need for tumor-free margins in resected tissue, and the individua'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 500 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 low-risk, early-stage breast cancer who are treated with cryoablation, the evidence includes systematic reviews, uncontrolled observational studies, and case series. Relevant outcomes are OS, disease-specific survival, quality of life, and treatment-related morbidity. The available evidence has shown that complete ablation can be achieved in most cases for variably defined small tumors, but studies have not included control groups or compared outcomes of cryosurgery with alternative strategies for managing similar individuals. Due to the lack of prospective controlled trials, it is not possible to conclude that cryoablation improves outcomes better than alternative treatments. 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 pancreas or bone who are treated with cryoablation, the evidence includes systematic reviews, 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 and unpublished 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	Mar 2026 (active, not recruiting)

NCT No.	Trial Name	Planned Enrollment	Completion Date
Breast cancer			
NCT05505643	COOL-IT: Cryoablation vs Lumpectomy in T1 Breast Cancers: A Randomized Controlled Trial With Safety Lead-in	256	Apr 2033 (recruiting)
NCT07483996	Cryoablation as Alternative for Lumpectomy in Early-Stage Breast Cancer: The CRYSTAL Trial	938	Dec 2038 (not yet recruiting)
Non-small cell lung cancer			
NCT07272356	Investigation of the Efficacy of Local Minimally Invasive Ablative Therapy for Pulmonary Tumors and Its Impact on Respiratory Function	68	Jun 2026 (active, not recruiting)
Unpublished			
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 (unknown)
NCT04334785	Evaluation for the Effectiveness and Safety of Cryo-ablation in the Treatment of Early Invasive Breast Cancer	186	May 2025 (unknown)
NCT05615545	Safety and Efficacy of Cryoablation in the Treatment of Advanced Bone and Soft Tissue Tumors: a Single-center Retrospective Study	30	Oct 2024 (unknown)

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 effective and safe alternative [to surgical resection] for the treatment of small, localized RCC." [52, 53] 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 the evaluation and management of clinically localized sporadic renal masses suspicious for RCC.[54] 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 percutaneous technique is preferred over a surgical approach whenever feasible to minimize morbidity.	Moderate	C
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 excision, 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

Breast Cancer

The National Comprehensive Network (NCCN) guideline on breast cancer does not include information on the use of cryoablation for breast cancer, except for ovarian ablation.[55]

Kidney Cancer

The NCCN (v.2.2026) guideline on kidney cancer states that "percutaneous ablation (cryosurgery, radiofrequency ablation, microwave ablation) is an option for the management of clinical stage T1 renal lesions. Percutaneous ablation is suitable for renal masses ≤ 3 cm. Percutaneous ablation is an option for clinical T1b masses in select patients not eligible for surgery. Biopsy of lesions is recommended to be done prior to or at time of ablation. Percutaneous ablation may require retreatment to achieve the same local oncologic outcomes as conventional surgery."

The NCCN guideline also notes that "active surveillance and percutaneous ablation such as cryotherapy, microwave ablation, or radiofrequency ablation are alternative strategies for selected patients, 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 percutaneous ablation with surgical resection (i.e., radical or partial nephrectomy by open or laparoscopic techniques) has not been performed."[56]

Non-Small Cell Lung Cancer

The NCCN (v.5.2026) guidelines for NSCLC made the following relevant recommendations:[57]

- 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 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.
- There is evidence on the use of IGTA for selected individuals with stage IA NSCLC, those who present with multiple lung cancers, or those who present with locoregional recurrence of symptomatic local thoracic disease.
- 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.1.2026) 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."[58]

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

References

1. Gao H, Zhou L, Zhang J, et al. Comparative efficacy of cryoablation versus robot-assisted partial nephrectomy in the treatment of cT1 renal tumors: a systematic review and meta-analysis. BMC Cancer. Sep 16 2024; 24(1): 1150. PMID 39285347
2. Yanagisawa T, Mori K, Kawada T, et al. Differential efficacy of ablation therapy versus partial nephrectomy between clinical T1a and T1b renal tumors: A systematic review and meta-analysis. Urol Oncol. Jul 2022; 40(7): 315-330. PMID 35562311
3. Uhlig J, Strauss A, Rücker G, et al. Partial nephrectomy versus ablative techniques for small renal masses: a systematic review and network meta-analysis. Eur Radiol. Mar 2019; 29(3): 1293-1307. PMID 30255245
4. Klatte T, Shariat SF, Remzi M. Systematic review and meta-analysis of perioperative and oncologic outcomes of laparoscopic cryoablation versus laparoscopic partial nephrectomy for the treatment of small renal tumors. J Urol. May 2014; 191(5): 1209-17. PMID 24231845
5. Tang K, Yao W, Li H, et al. Laparoscopic renal cryoablation versus laparoscopic partial nephrectomy for the treatment of small renal masses: a systematic review and meta-analysis of comparative studies. J Laparoendosc Adv Surg Tech A. Jun 2014; 24(6): 403-10. PMID 24914926
6. Andrews JR, Atwell T, Schmit G, et al. Oncologic Outcomes Following Partial Nephrectomy and Percutaneous Ablation for cT1 Renal Masses. Eur Urol. Aug 2019; 76(2): 244-251. PMID 31060824
7. Rembeyo G, Correas JM, Jantzen R, et al. Percutaneous Ablation Versus Robotic Partial Nephrectomy in the Treatment of cT1b Renal Tumors: Oncologic and Functional Outcomes of a Propensity Score-weighted Analysis. Clin Genitourin Cancer. Apr 2020; 18(2): 138-147. PMID 31982346
8. Yan S, Yang W, Zhu CM, et al. Comparison among cryoablation, radiofrequency ablation, and partial nephrectomy for renal cell carcinomas sized smaller than 2 cm or sized 2-4 cm: A population-based study. Medicine (Baltimore). May 2019; 98(21): e15610. PMID 31124938
9. Pecoraro A, Palumbo C, Knipper S, et al. Cryoablation Predisposes to Higher Cancer Specific Mortality Relative to Partial Nephrectomy in Patients with Nonmetastatic pT1b Kidney Cancer. J Urol. Dec 2019; 202(6): 1120-1126. PMID 31347950
10. Cronan J, Dariushnia S, Bercu Z, et al. Systematic Review of Contemporary Evidence for the Management of T1 Renal Cell Carcinoma: What IRs Need to Know for Kidney Cancer Tumor Boards. Semin Intervent Radiol. Aug 2019; 36(3): 194-202. PMID 31435127
11. Morkos J, Porosnicu Rodriguez KA, Zhou A, et al. Percutaneous Cryoablation for Stage 1 Renal Cell Carcinoma: Outcomes from a 10-year Prospective Study and Comparison with Matched Cohorts from the National Cancer Database. Radiology. Aug 2020; 296(2): 452-459. PMID 32515677
12. Stacul F, Sachs C, Giudici F, et al. Cryoablation of renal tumors: long-term follow-up from a multicenter experience. Abdom Radiol (NY). Sep 2021; 46(9): 4476-4488. PMID 33912986
13. Pickersgill NA, Vetter JM, Mittauer DJ, et al. Intermediate-Term Oncologic Outcomes of Partial Nephrectomy vs Cryoablation in Renal Tumors 3 cm: A Propensity Score-Matched Analysis. J Urol. Jul 2025; 214(1): 32-40. PMID 40073100

14. Lee SH, Choi WJ, Sung SW, et al. Endoscopic cryotherapy of lung and bronchial tumors: a systematic review. Korean J Intern Med. Jun 2011; 26(2): 137-44. PMID 21716589

15. Niu L, Xu K, Mu F. Cryosurgery for lung cancer. J Thorac Dis. Aug 2012; 4(4): 408-19. PMID 22934144

16. Callstrom MR, Woodrum DA, Nichols FC, et al. Multicenter Study of Metastatic Lung Tumors Targeted by Interventional Cryoablation Evaluation (SOLSTICE). J Thorac Oncol. Jul 2020; 15(7): 1200-1209. PMID 32151777

17. de Baere T, Tselikas L, Woodrum D, et al. Evaluating Cryoablation of Metastatic Lung Tumors in Patients--Safety and Efficacy: The ECLIPSE Trial--Interim Analysis at 1 Year. J Thorac Oncol. Oct 2015; 10(10): 1468-74. PMID 26230972

18. de Baère T, Woodrum D, Tselikas L, et al. The ECLIPSE Study: Efficacy of Cryoablation on Metastatic Lung Tumors With a 5-Year Follow-Up. J Thorac Oncol. Nov 2021; 16(11): 1840-1849. PMID 34384914

19. Moore W, Talati R, Bhattacharji P, et al. Five-year survival after cryoablation of stage I non-small cell lung cancer in medically inoperable patients. J Vasc Interv Radiol. Mar 2015; 26(3): 312-9. PMID 25735518

20. Ratko TA, Vats V, Brock J, et al. Local Nonsurgical Therapies for Stage I and Symptomatic Obstructive Non- Small-Cell Lung Cancer (AHRQ Comparative Effectiveness Review No. 112). Rockville, MD: Agency for Healthcare Research and Quality; 2013.

21. Maiwand MO, Asimakopoulos G. Cryosurgery for lung cancer: clinical results and technical aspects. Technol Cancer Res Treat. Apr 2004; 3(2): 143-50. PMID 15059020

22. Tan E, Chong J, Pua U, et al. Local recurrence and residual tumor rates following cryoablation for small early-stage breast cancers: systemic review and meta-analysis. Breast Cancer. Jan 2025; 32(1): 69-78. PMID 39425821

23. Zhao Z, Wu F. Minimally-invasive thermal ablation of early-stage breast cancer: a systemic review. Eur J Surg Oncol. Dec 2010; 36(12): 1149-55. PMID 20889281

24. Holmes DR, Manoian S, Rahman RL, et al. Cryoablation: A Minimally Invasive Alternative for Early-Stage Breast Cancer: 6-Year Outcomes of the FROST Clinical Trial. Ann Surg Oncol. Apr 2026; 33(4): 3374-3382. PMID 41538117

25. Fine RE, Gilmore RC, Dietz JR, et al. Cryoablation Without Excision for Low-Risk Early-Stage Breast Cancer: 3-Year Interim Analysis of Ipsilateral Breast Tumor Recurrence in the ICE3 Trial. Ann Surg Oncol. Oct 2021; 28(10): 5525-5534. PMID 34392462

26. Fine RE, Gilmore RC, Tomkovich KR, et al. Cryoablation Without Excision for Early-Stage Breast Cancer: ICE3 Trial 5-Year Follow-Up on Ipsilateral Breast Tumor Recurrence. Ann Surg Oncol. Oct 2024; 31(11): 7273-7283. PMID 39283572

27. Simmons RM, Ballman KV, Cox C, et al. A Phase II Trial Exploring the Success of Cryoablation Therapy in the Treatment of Invasive Breast Carcinoma: Results from ACOSOG (Alliance) Z1072. Ann Surg Oncol. Aug 2016; 23(8): 2438-45. PMID 27221361

28. Niu L, Mu F, Zhang C, et al. Cryotherapy protocols for metastatic breast cancer after failure of radical surgery. Cryobiology. Aug 2013; 67(1): 17-22. PMID 23619024

29. Manenti G, Perretta T, Gaspari E, et al. Percutaneous local ablation of unifocal subclinical breast cancer: clinical experience and preliminary results of cryotherapy. Eur Radiol. Nov 2011; 21(11): 2344-53. PMID 21681574

30. Pusztaszeri M, Vlastos G, Kinkel K, et al. Histopathological study of breast cancer and normal breast tissue after magnetic resonance-guided cryotherapy ablation. Cryobiology. Aug 2007; 55(1): 44-51. PMID 17604016

31. Sabel MS, Kaufman CS, Whitworth P, et al. Cryoablation of early-stage breast cancer: work-in-progress report of a multi-institutional trial. Ann Surg Oncol. May 2004; 11(5): 542-9. PMID 15123465

32. Tanaka S. Cryosurgical treatment of advanced breast cancer. Skin Cancer. Jan 1995;10:9-18.

33. Pfleiderer SO, Freesmeyer MG, Marx C, et al. Cryotherapy of breast cancer under ultrasound guidance: initial results and limitations. Eur Radiol. Dec 2002; 12(12): 3009-14. PMID 12439583

34. Suzuki Y. Cryosurgical treatment of advanced breast cancer and cryoimmunological responses. Skin Cancer. 1995;10:19-26.

35. Morin J, Traoré A, Dionne G, et al. Magnetic resonance-guided percutaneous cryosurgery of breast carcinoma: technique and early clinical results. Can J Surg. Oct 2004; 47(5): 347-51. PMID 15540687

36. Kaufman CS, Bachman B, Littrup PJ, et al. Office-based ultrasound-guided cryoablation of breast fibroadenomas. Am J Surg. Nov 2002; 184(5): 394-400. PMID 12433600

37. Kaufman CS, Littrup PJ, Freman-Gibb LA, et al. Office-based cryoablation of breast fibroadenomas: 12-month followup. J Am Coll Surg. Jun 2004; 198(6): 914-23. PMID 15194073

38. Kaufman CS, Bachman B, Littrup PJ, et al. Cryoablation treatment of benign breast lesions with 12-month follow-up. Am J Surg. Oct 2004; 188(4): 340-8. PMID 15474424

39. Littrup PJ, Freeman-Gibb L, Andea A, et al. Cryotherapy for breast fibroadenomas. Radiology. Jan 2005; 234(1): 63-72. PMID 15550369

40. Kaufman CS, Littrup PJ, Freeman-Gibb LA, et al. Office-based cryoablation of breast fibroadenomas with long-term follow-up. Breast J. 2005; 11(5): 344-50. PMID 16174156

41. Nurko J, Mabry CD, Whitworth P, et al. Interim results from the FibroAdenoma Cryoablation Treatment Registry. Am J Surg. Oct 2005; 190(4): 647-51; discussion 651-2. PMID 16164941

42. Tao Z, Tang Y, Li B, et al. Safety and effectiveness of cryosurgery on advanced pancreatic cancer: a systematic review. Pancreas. Jul 2012; 41(5): 809-11. PMID 22695092

43. Keane MG, Bramis K, Pereira SP, et al. Systematic review of novel ablative methods in locally advanced pancreatic cancer. World J Gastroenterol. Mar 07 2014; 20(9): 2267-78. PMID 24605026

44. Xue K, Liu X, Xu X, et al. Perioperative outcomes and long-term survival of cryosurgery on unresectable pancreatic cancer: a systematic review and meta-analysis. Int J Surg. Jul 01 2024; 110(7): 4356-4369. PMID 38537056

45. Li J, Chen X, Yang H, et al. Tumour cryoablation combined with palliative bypass surgery in the treatment of unresectable pancreatic cancer: a retrospective study of 142 patients. Postgrad Med J. Feb 2011; 87(1024): 89-95. PMID 21131612

46. Xu KC, Niu LZ, Hu YZ, et al. A pilot study on combination of cryosurgery and (125)iodine seed implantation for treatment of locally advanced pancreatic cancer. World J Gastroenterol. Mar 14 2008; 14(10): 1603-11. PMID 18330956

47. Kovach SJ, Hendrickson RJ, Cappadona CR, et al. Cryoablation of unresectable pancreatic cancer. Surgery. Apr 2002; 131(4): 463-4. PMID 11935137

48. Alaqeel M, Alnajres A, Mulia Y, et al. Radiofrequency Ablation and Cryoablation in Treating Painful Bone Metastasis: A Comprehensive Systematic Review and Separate Single-Arm Meta-analysis. Orthop Rev (Pavia). 2025; 17: 150315. PMID 41450487

49. Meller I, Weinbroum A, Bickels J, et al. Fifteen years of bone tumor cryosurgery: a single-center experience of 440 procedures and long-term follow-up. Eur J Surg Oncol. Aug 2008; 34(8): 921-927. PMID 18158228

50. Callstrom MR, Dupuy DE, Solomon SB, et al. Percutaneous image-guided cryoablation of painful metastases involving bone: multicenter trial. Cancer. Mar 01 2013; 119(5): 1033-41. PMID 23065947

51. Jennings JW, Prologo JD, Garnon J, et al. Cryoablation for Palliation of Painful Bone Metastases: The MOTION Multicenter Study. Radiol Imaging Cancer. Mar 2021; 3(2): e200101. PMID 33817650

52. Purysko AS, Nikolaidis P, Khatri G, et al. ACR Appropriateness Criteria® Post-Treatment Follow-up and Active Surveillance of Clinically Localized Renal Cell Carcinoma: 2021 Update. J Am Coll Radiol. May 2022; 19(5S): S156-S174. PMID 35550799

53. American College of Radiology (ACR). ACR Appropriateness Criteria: Post-treatment follow-up and active surveillance of clinically localized renal cell carcinoma. Updated 2021. **https://acsearch.acr.org/docs/69365/Narrative/**. Accessed August 11, 2026.

54. Campbell SC, Clark PE, Chang SS, et al. Renal Mass and Localized Renal Cancer: Evaluation, Management, and Follow-Up: AUA Guideline: Part I. J Urol. Aug 2021; 206(2): 199-208. PMID 34115547

55. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version 3.2026. **https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf**. Accessed August 11, 2026.

56. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Kidney Cancer. Version 2.2026. http://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf. Accessed August 11, 2026.

57. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer. Version 5.2026. **http://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf**. Accessed August 11, 2026.

58. National Comprehensive Cancer Network. Adult Cancer Pain. Version 1.2026. **https://www.nccn.org/professionals/physician_gls/pdf/pain.pdf**. Accessed August 11, 2026

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.

Date	Comments
10/01/25	Annual Review, approved September 8, 2025. Policy updated with literature review through June 3, 2025; references added. Policy statements unchanged.
10/01/26	Annual Review, approved September 7, 2026. Policy updated with literature review through May 18, 2026; references added. Policy statements reformatted for clarity and to include stand-alone statement for breast indications. Intent otherwise 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. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2026 Premera All Rights Reserved.

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.