



MASSACHUSETTS

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Medical Policy

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

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Policy Number: 260

BCBSA Reference Number: 7.01.92 (For Plan internal use only)

Related Policies

- Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors, #[259](#)
- Cryosurgical Ablation of Primary or Metastatic Liver Tumors, #[633](#)
- Radiofrequency Ablation of Primary or Metastatic Liver Tumors, #[286](#)
- Cryoablation of Prostate Cancer, #[149](#)

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO BlueSM and Medicare PPO BlueSM Members

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 (ie, the individual has 1 kidney or renal insufficiency defined by a glomerular filtration rate [GFR] of less than 60 mL/min per m²), and standard surgical approach (ie, resection of renal tissue) is likely to worsen kidney function substantially, or
- The individual 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 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.

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

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is not required .
Commercial PPO and Indemnity	Prior authorization is not required .
Medicare HMO Blue SM	Prior authorization is not required .
Medicare PPO Blue SM	Prior authorization is not required .

CPT Codes / HCPCS Codes / ICD Codes

The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The above **medical necessity criteria MUST** be met for the following codes to be covered for **Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:**

CPT Codes

CPT codes:	Code Description
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, 1 or more renal mass lesion(s), cryosurgical, including intraoperative ultrasound guidance and monitoring, if performed
50542	Laparoscopy, surgical; ablation of renal mass lesion(s), including intraoperative ultrasound guidance and monitoring, when performed
50593	Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy
76940	Ultrasound guidance for, and monitoring of, parenchymal tissue ablation
77013	Computed tomography guidance for, and monitoring of, parenchymal tissue ablation
77022	Magnetic resonance guidance for, and monitoring of, parenchymal tissue ablation

The following CPT code is considered investigational for **Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:**

CPT Codes

CPT codes:	Code Description
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 (eg, metastasis) including adjacent soft tissue when involved by tumor extension, percutaneous, including imaging guidance when performed; cryoablation

Description

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 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 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 the 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 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

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.

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.

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 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 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 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. 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.

Policy History

Date	Action
9/2024	Annual policy review. Policy updated with literature review through June 3, 2024; no references added, guidelines updated. Policy statements unchanged.
9/2023	Annual policy review. References added. Policy statements unchanged.
9/2022	Annual policy review. No references added. Terminology in policy statements changed from "patients" to "individuals" for standardization; intent unchanged.
2/2022	Clarified coding information.
9/2021	Annual policy review. 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.
9/2020	Annual policy review. Description, summary and references updated. Policy statements unchanged.
1/2020	Clarified coding information.
9/2019	Annual policy review. Description, summary and references updated. Policy statements unchanged.
9/2018	Annual policy review. No changes to policy statements. New references added. Background and summary clarified.
4/2018	Annual policy review. Medically necessary policy statements for lung cancer added. Clarified coding information. Effective 4/1/2018.
1/2018	Clarified coding information.
10/2016	Annual policy review. New references added.
8/2015	Annual policy review. New references added.
9/2014	Annual policy review. New references added.
6/2014	Updated Coding section with ICD10 procedure and diagnosis codes. Effective 10/2015.

10/2013	Annual policy review. New references added.
11/2011 -4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
10/2011	Reviewed - Medical Policy Group - GI, Nutrition, and Organ Transplantation. No changes to policy statements.
9/2011	Reviewed - Medical Policy Group - Urology, Obstetrics, and Gynecology. No changes to policy statements.
7/2011	Reviewed - Medical Policy Group - Hematology and Oncology. No changes to policy statements.
11/2010	Reviewed - Medical Policy Group - Gastroenterology, Nutrition, and Organ Transplantation. No changes to policy statements.
9/2010	Reviewed - Medical Policy Group - Hematology and Oncology. No changes to policy statements.
9/2010	Medical policy #260 describing covered and non-covered indications. Effective 9/2010.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

References

1. 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
2. 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
3. Klätte 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
4. 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
5. 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
6. 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
7. Yan S, Yang W, Zhu CM, et al. Comparison among cryoablation, radiofrequency ablation, and partial nephrectomy for renal cell carcinomas sized smaller than 2cm or sized 2-4cm: A population-based study. *Medicine (Baltimore)*. May 2019; 98(21): e15610. PMID 31124938
8. 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
9. 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
10. 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
11. 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

12. 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
13. Niu L, Xu K, Mu F. Cryosurgery for lung cancer. *J Thorac Dis.* Aug 2012; 4(4): 408-19. PMID 22934144
14. 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
15. 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
16. 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
17. 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.
18. 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
19. 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
20. 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
21. 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
22. 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
23. 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
24. 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
25. Tanaka S. Cryosurgical treatment of advanced breast cancer. *Skin Cancer.* Jan 1995;10:9-18.
26. 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
27. Suzuki Y. Cryosurgical treatment of advanced breast cancer and cryoimmunological responses. *Skin Cancer.* 1995;10:19-26.
28. 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
29. 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
30. Kaufman CS, Littrup PJ, Freeman-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
31. 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
32. Littrup PJ, Freeman-Gibb L, Andea A, et al. Cryotherapy for breast fibroadenomas. *Radiology.* Jan 2005; 234(1): 63-72. PMID 15550369
33. 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
34. 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
35. 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
36. 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

37. 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
38. 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
39. Kovach SJ, Hendrickson RJ, Cappadona CR, et al. Cryoablation of unresectable pancreatic cancer. *Surgery*. Apr 2002; 131(4): 463-4. PMID 11935137
40. 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
41. 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
42. 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
43. 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
44. 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 June 3, 2024.
45. 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
46. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Kidney Cancer. Version 4.2024. http://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf. Accessed June 3, 2024.
47. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer. Version 5.2024. http://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed June 2, 2024.
48. National Comprehensive Cancer Network. Adult Cancer Pain. Version 2.2024. https://www.nccn.org/professionals/physician_gls/pdf/pain.pdf. Accessed June 1, 2024.