

Medical Coverage Policy | Cryosurgical Ablation of Miscellaneous Solid Tumors other than Renal, Liver and Prostate



EFFECTIVE DATE: 12|01|2021

POLICY LAST UPDATED: 08|16|2023

OVERVIEW

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.

This policy addresses cryosurgical ablation of miscellaneous solid tumors located in areas such as the breast, bone, pancreas and lung. For other solid tumors, please refer to the policies in the Related Policies section.

MEDICAL CRITERIA

Medicare Advantage Plans and Commercial Products

Cryosurgical ablation may be considered medically necessary to treat lung cancer when one 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.

PRIOR AUTHORIZATION

Prior authorization is required for Medicare Advantage Plans and recommended for Commercial Products for cryosurgical ablation as a treatment of lung cancer.

POLICY STATEMENT

Medicare Advantage Plans

Lung Tumors

Cryosurgical ablation may be considered medically necessary to treat lung cancer when the policy criteria is met.

Breast, Pancreas, or Bone Tumors

Cryosurgical ablation is not covered as a treatment for benign or malignant tumors of the breast, pancreas, or bone and other solid tumors or metastases, outside the liver, prostate, or renal tumor as the evidence is insufficient to determine the effects of the technology on health outcomes.

See the Related Policies section for policies specific to liver, prostate or renal tumor(s).

Commercial Products

Lung Tumors

Cryosurgical ablation may be considered medically necessary to treat lung cancer when the policy criteria is met.

Breast, Pancreas, or Bone Tumors

Cryosurgical ablation is not medically necessary as a treatment for benign or malignant tumors of the breast, pancreas, or bone and other solid tumors or metastases, outside the liver, prostate, or renal tumor as the evidence is insufficient to determine the effects of the technology on health outcomes.

See the Related Policies section for policies specific to liver, prostate or renal tumor.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable surgery or not medically necessary/not covered benefits/coverage.

BACKGROUND

Lung

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

The evidence on cryosurgery for lung cancer consists of studies that use cryosurgery for inoperable or metastatic disease. The available studies are small cohort studies and nonrandomized studies with relatively short-term follow-up as well as systematic reviews of these studies. Additionally, complications have frequently been reported and severe, but the true incidence of complications is uncertain and difficult to differentiate from manifestations of the underlying malignancy. Because available studies do not include control groups or compare outcomes of cryosurgery with alternative strategies for managing similar patients, no conclusions can be made on the net health outcome of cryosurgery for lung cancer.

Breast Tumor

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.

For the treatment of primary and recurrent breast cancer, 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 patients. Therefore, no conclusions can be made on the net health outcome of cryosurgery for breast cancer. For treatment of fibroadenomas, there is a small body of evidence. This evidence has demonstrated that most fibroadenomas become "nonpalpable" following cryoablation. However, there is a lack of comparative trials. Comparative trials with adequate long-term follow-up are needed to assess this technology and determine how this approach compares with surgery, as well as with vacuum-assisted excision and with observation (approximately one-third of fibroadenomas regress over time after cryoablation).

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 focuses on slowing tumor growth and palliation of symptoms.

The available evidence on cryosurgery for pancreatic cancer consists of retrospective case series that used cryosurgery for palliation of inoperable disease and a systematic review of these studies. These studies reported that pain relief was achieved in most cases and that complications (eg, delayed gastric emptying) are common, but the true rate of complications is uncertain. Because these studies did not include control groups

or compare outcomes of cryosurgery with alternative strategies for managing similar patients, no conclusions can be made on the net health outcome of cryosurgery for pancreatic cancer.

Bone Cancers

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

For individuals who have solid tumors (of the breast, pancreas, and bone) who are treated with cryoablation, the evidence includes uncontrolled observational studies and case series. Relevant outcomes are overall survival, 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 the effects of the technology on health outcomes.

CODING

Medicare Advantage Plans and Commercial Products

The following code(s) is covered when the policy criteria is met:

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

The following code(s) are not covered for Medicare Advantage Plans and not medically necessary for Commercial Products;

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

0581T Ablation, malignant breast tumor(s), percutaneous, cryotherapy, including imaging guidance when performed, unilateral

RELATED POLICIES

Cryosurgical Ablation of Primary or Metastatic Liver Tumors

Prior Authorization via Web-Based Tool for Procedures

Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors

Whole Gland Cryoablation of Prostate Cancer

PUBLISHED

Provider Update, October 2023

Provider Update, October 2022

Provider Update, October 2021

Provider Update, September 2021

Provider Update, September 2020

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. 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
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. Pfliederer 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. Puryrsko 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 6, 2023.

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 4.2023. http://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf. Accessed June 6, 2023.
47. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer. Version 3.2023. http://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed June 5, 2023.
48. National Comprehensive Cancer Network. Adult Cancer Pain. Version 1. 2023. https://www.nccn.org/professionals/physician_gls/pdf/pain.pdf. Accessed June 4, 2023.

CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS

This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member's subscriber agreement or member certificate and/or the employer agreement, and those documents will supersede the provisions of this medical policy. For information on member-specific benefits, call the provider call center. If you provide services to a member which are determined to not be medically necessary (or in some cases medically necessary services which are non-covered benefits), you may not charge the member for the services unless you have informed the member and they have agreed in writing in advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice. Blue Cross & Blue Shield of Rhode Island is an independent licensee of the Blue Cross and Blue Shield Association.

