

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



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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 policy section.

MEDICAL CRITERIA

BlueCHIP for Medicare and Commercial Products

Cryosurgical ablation may be considered medically necessary to treat lung cancer when one of the following criteria is met:

- The patient has early-stage non-small-cell lung cancer and is a poor surgical candidate; or
- The patient requires palliation for a central airway obstructing lesion.

PRIOR AUTHORIZATION

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

POLICY STATEMENT

BlueCHIP for Medicare 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 policy section for policies specific to liver, prostate or renal tumor.

Commercial Products

Lung Tumors

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

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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. 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

There is a small amount of literature on cryoablation for bone cancers. This evidence base consists of case series and is inadequate to determine efficacy for any of the indications studied.

Summary

For individuals who have solid tumors (located in areas of the breast, pancreas, bone) who receive cryosurgical ablation, the evidence includes nonrandomized comparative studies, case series, and systematic reviews of these nonrandomized studies. Relevant outcomes are overall survival, disease-specific survival, quality of life, and treatment-related morbidity. There is a lack of randomized controlled trials and high-quality comparative studies to determine the efficacy and comparative effectiveness of cryoablation. The largest amount of evidence assesses renal cell carcinoma in select patients (ie, those with small tumors who are not surgical candidates, or those who have baseline renal insufficiency of such severity that standard surgical procedures would impair their kidney function). Cryoablation results in short-term tumor control and less morbidity than surgical resection, but long-term outcomes may be inferior to surgery. For other indications, there is less evidence, with single-arm series reporting high rates of local control. Due to the lack of prospective controlled trials, it is difficult to conclude that cryoablation improves outcomes for any indication better than alternative treatments. The evidence is insufficient to determine the effects of the technology on health outcomes.

CODING

BlueCHiP for Medicare and Commercial Products

The following code 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 codes are not covered for BlueCHiP for Medicare 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

RELATED POLICIES

Cryosurgical Ablation of Primary or Metastatic Liver Tumors

Whole Gland Cryoablation of Prostate Cancer

Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors

Prior Authorization of Procedures

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REFERENCES:

1. Zhao Z, Wu F. Minimally-invasive thermal ablation of early-stage breast cancer: a systemic review. *Eur J Surg Oncol.* Dec 2010;36(12):1149-1155. PMID 20889281
2. 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):2438-2445. PMID 27221361
3. 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
4. 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):2344-2353. PMID 21681574

5. 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
6. 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):542-549. PMID 15123465
7. Tanaka S. Cryosurgical treatment of advanced breast cancer. *Skin Cancer*. Jan 1995;10:9-18.
8. Pfliegerer SO, Freesmeyer MG, Marx C, et al. Cryotherapy of breast cancer under ultrasound guidance: initial results and limitations. *Eur Radiol*. Dec 2002;12(12):3009-3014. PMID 12439583
9. Suzuki Y. Cryosurgical treatment of advanced breast cancer and cryoimmunological responses. *Skin Cancer*. 1995;10:19-26. PMID
10. Morin J, Traore 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):347-351. PMID 15540687
11. 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
12. 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):914-923. PMID 15194073
13. 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):340-348. PMID 15474424
14. Littrup PJ, Freeman-Gibb L, Andea A, et al. Cryotherapy for breast fibroadenomas. *Radiology*. Jan 2005;234(1):63-72. PMID 15550369
15. Kaufman CS, Littrup PJ, Freeman-Gibb LA, et al. Office-based cryoablation of breast fibroadenomas with long-term follow-up. *Breast J*. Sep-Oct 2005;11(5):344-350. PMID 16174156
16. 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):809-811. PMID 22695092
17. Keane MG, Bramis K, Pereira SP, et al. Systematic review of novel ablative methods in locally advanced pancreatic cancer. *World J Gastroenterol*. Mar 7 2014;20(9):2267-2278. PMID 24605026
18. 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
19. 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):1603-1611. PMID 18330956
20. Kovach SJ, Hendrickson RJ, Cappadona CR, et al. Cryoablation of unresectable pancreatic cancer. *Surgery*. Apr 2002;131(4):463-464. PMID 11935137
21. 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
22. Callstrom MR, Dupuy DE, Solomon SB, et al. Percutaneous image-guided cryoablation of painful metastases involving bone: multicenter trial. *Cancer*. Mar 1 2013;119(5):1033-1041. PMID 23065947

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