

DRAFT 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|2021

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

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 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 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 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.

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 policy 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. 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

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

Whole Gland Cryoablation of Prostate Cancer

Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors

Prior Authorization via Web-Based Tool for Procedures

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