Corporate Medical Policy

Cryosurgical Ablation of Miscellaneous Solid Tumors Other Than Liver, Prostate, or Dermatologic Tumors

File Name: cryosurgical_ablation_of_miscellaneous_solid_tumors
Origination: 1/2007
Last Review: 4/2022

Description of Procedure or Service

Cryosurgical ablation (also referred to as cryosurgery or cryoablation) involves freezing of target tissues, most often by inserting into the tumor a probe through which coolant is circulated. Cryosurgery may be performed as an open surgical technique or as a closed procedure under laparoscopic or ultrasound guidance.

The hypothesized advantages of cryosurgery include improved local control and benefits common to any minimally invasive procedure (e.g., preserving normal organ tissue, decreasing morbidity, decreasing length of hospitalization). Potential complications of cryosurgery include those caused by hypothermic damage to normal tissue adjacent to the tumor, structural damage along the probe track, and secondary tumors, if cancerous cells are seeded during probe removal.

Cryosurgical treatment of various tumors including renal cell carcinoma (RCC), malignant and benign breast disease, pancreatic cancer, bone cancer, and lung cancer has been reported in the literature.

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 radiation therapy 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 either present as a palpable mass or a mammographic abnormality. These benign tumors are frequently surgically excised to rule out a malignancy.

Renal cell carcinoma: Localized RCC is treated by radical nephrectomy or nephron-sparing surgery. Prognosis drops precipitously if the tumor extends outside the kidney capsule, since chemotherapy is relatively ineffective against metastatic RCC.

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. This is rarely curative but rather seeks to retard tumor growth or palliate symptoms.

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 radiation treatment 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. This is rarely curative but rather seeks to retard tumor growth or palliate 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.

This policy is specific to solid tumors other than the liver, prostate, or dermatologic tumors. Refer to the medical policy entitled, Cryosurgical Ablation of Primary or Metastatic Liver Tumors for information specific to the liver, Focal Treatments for Prostate Cancer, and Whole Gland Ablative Treatments of Prostate Cancer for the use of cryoablation in the prostate.

Regulatory Status
There are several cryoablation devices cleared for marketing by the U.S. 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 by Endocare;
- CryoGen Cryosurgical System by Cryosurgical, Inc.;
- CryoHit® by Galil Medical for the treatment of breast fibroadenoma;
- IceSense3™, ProSense™, and MultiSense Systems by IceCure Medical;
- SeedNet™ System by Galil Medical; and
- Visica® System by Sanarus Medical.

Related Policies:
Cryosurgical Ablation of Primary or Metastatic Liver Tumors
Focal Treatments for Prostate Cancer
Whole Gland Ablative Treatments of Prostate Cancer

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for cryosurgical ablation of renal cell carcinoma and lung cancer when it is determined to be medically necessary because the medical criteria and guidelines noted below are met.

Cryosurgical ablation is considered investigational as a treatment of benign or malignant breast tumors, renal cell carcinomas in patients who are surgical candidates, pancreatic cancer, bone or other solid tumors or metastases outside the liver . BCBSNC does not cover investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Cryosurgical Ablation of Miscellaneous Solid Tumors is covered

Cryosurgical Ablation of Miscellaneous Solid Tumors Other Than Liver, Prostate, or Dermatologic Tumors

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 patient has one kidney or renal insufficiency defined by a glomerular filtration rate [GFR] of less than 60 mL/min per m^2) and standard surgical approach (i.e., resection of renal tissue) is likely to substantially worsen kidney function; or
- Patient 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 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.

When Cryosurgical Ablation of Miscellaneous Solid Tumors is not covered

Cryosurgical ablation is considered investigational as a treatment of benign or malignant tumors of the breast, pancreas, or bone and other solid tumors or metastases outside the liver and to treat renal cell carcinomas in patients who are surgical candidates.

Policy Guidelines

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 overall survival, 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 overall survival, 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 hemoptypsis 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.

Cryosurgical Ablation of Miscellaneous Solid Tumors Other Than Liver, Prostate, or Dermatologic Tumors

For individuals with non-small cell lung cancer who require palliation for a central airway obstructing lesion who are treated with cryoablation, the evidence includes case series. Relevant outcomes are overall survival, 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 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 that the technology results in an improvement in the net health outcome.

Clinical input obtained in 2017 supports that the following indications provide a clinically meaningful improvement in net health outcome and are consistent with generally accepted medical practice.

- Use of cryosurgical ablation to manage individuals with localized renal cell cancer when either of the following criteria is met:
    - No more than 4 cm in size when preservation of kidney function is necessary (i.e., the patient has 1 kidney or renal insufficiency defined by a glomerular filtration rate < 60 $mL/min/m^2$), and standard surgical approach (i.e., resection of renal tissue) is likely to worsen kidney function substantially; or
    - When the patient is not considered a surgical candidate.
- Use of cryosurgical ablation to manage individuals with lung cancer when either of the following criteria is met:
    - Poor surgical candidates with early-stage non-small-cell lung cancer; or
    - Palliation of a central airway obstructing lesion.

Thus, the above indications may be considered medically necessary considering the suggestive evidence and clinical input support.

However, the clinical input does not support whether the following indication provides a clinically meaningful improvement in the net health outcome or is consistent with generally accepted medical practice.

- Use of cryosurgical ablation to manage individuals with:
    - Malignant or benign tumors of the breast;
    - Pancreatic cancer; or
    - Bone cancer.

Thus, the above indication may be considered investigational.

There was strong clinical support for cryoablation in patients with small renal cell cancers who are either poor surgical candidates or whose kidney function is likely to be substantially impaired by surgery. Moreover, there was clinical support for cryoablation in patients who were either poor surgical candidates with early-stage non-small cell lung cancer or who required palliation for a lesion obstructing the central airway. Contextual factors contributing to this support include the lack of treatment alternatives and the potential for reduced harm compared to surgery.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: *0581T, 19105, 20983, 32994, 50250, 50542, 50593*

There is no specific code describing cryosurgical ablation of pancreatic tumors. Providers should bill the most appropriate unlisted code, such as 48999.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

From Policy Entitled: Cryosurgical Ablation of Solid Tumors Other Than Liver or Prostate

BCBSA Medical Policy Reference Manual, 7.01.92, 4/25/06

ECRI Hotline Response - Cryosurgery for Breast Cancer and Breast Fibroadenoma (04/29/2005) retrieved on 11/3/06 from http://www.ta.ecri.org/Hotline/Prod/summary/archive.aspx?doc_id=7409

Specialty Matched Consultant Advisory Panel - 5/8/2007 (Renal Cell Cancer)

Policy retitled: Cryosurgical Ablation of Solid Tumors of the Breast or Pancreas

BCBSA Medical Policy Reference Manual, 7.01.92, 8/2/07

Specialty Matched Consultant Advisory Panel - 9/4/08

BCBSA Medical Policy Reference Manual, 7.01.92, 6/10/10

Medical Director review, April 2011

Policy retitled: Cryosurgical Ablation of Solid Tumors of the Breast, Pancreas, or Lung

BCBSA Medical Policy Reference Manual, 7.01.92, 7/14/2011

Medical Director review, 11/2011

Policy retitled: Cryosurgical Ablation of Miscellaneous Solid Tumors Other Than Liver, Prostate, or Dermatologic Tumors

Specialty Matched Consultant Advisory Panel – 5/16/12

BCBSA Medical Policy Reference Manual, 7.01.92, 7/12/2012

Medical Director review 9/2012

Specialty Matched Consultant Advisory Panel – 5/15/13

BCBSA Medical Policy Reference Manual, 7.01.92, 7/11/2013

Specialty Matched Consultant Advisory Panel – 5/27/14

BCBSA Medical Policy Reference Manual, 7.01.92, 7/10/2014

Specialty Matched Consultant Advisory Panel – 5/2015

BCBSA Medical Policy Reference Manual, 7.01.92, 7/9/2015

Specialty Matched Consultant Advisory Panel – 5/2016

BCBSA Medical Policy Reference Manual, 7.01.92, 8/11/2016

Specialty Matched Consultant Advisory Panel – 5/2017

BCBSA Medical Policy Reference Manual, 7.01.92, 11/9/2017

Specialty Matched Consultant Advisory Panel – 5/2018

BCBSA Medical Policy Reference Manual, 7.01.92, 7/12/2018

Specialty Matched Consultant Advisory Panel – 6/2019

BCBSA Medical Policy Reference Manual, 7.01.92, 7/11/2019

Specialty Matched Consultant Advisory Panel – 5/2020

BCBSA Medical Policy Reference Manual, 7.01.92, 7/16/2020

Specialty Matched Consultant Advisory Panel – 4/2021

BCBSA Medical Policy Reference Manual, 7.01.92, 7/8/2021

Specialty Matched Consultant Advisory Panel – 4/2022

Policy Implementation/Update Information

From Policy Entitled: Cryosurgical Ablation of Solid Tumors Other Than Liver or Prostate

1/3/07 New policy issued. (pmo)

1/29/07 CPT code 50592 removed from Billing/Coding section. Code is not applicable to this policy. CPT code 50542 added to Billing/Coding section. Effective 4/1/07, CPT code 50542 will require prior plan approval and will be considered investigational when cryosurgical ablation is used as a technique for ablating renal cell carcinoma. Notification given 1/29/07. Effective date 4/9/07. (pmo)

6/4/07 Specialty Matched Consultant Advisory Panel review 5/2007 (Renal Cell Cancer). No changes to criteria. Reference source added. (pmo)

12/31/07 Under Billing/Coding section removed CPT code 0135T and added new code 50593 to be effective January 1, 2008. (pmo)

Policy retitled: Cryosurgical Ablation of Solid Tumors of the Breast or Pancreas

2/11/08 Cryoablation for Renal Cell Cancer (RCC) has been combined with the policy for radiofrequency ablation of RCC (policy number SUR6576). Cryoablation for RCC has been deleted from this policy (SUR6181). Description, Policy, Policy Guidelines, Key Words, Medical Term Definitions, etc. revised as necessary to remove references to cryoablation of RCC. (pmo)

10/6/08 No changes to criteria. Reference source added. Specialty Matched Consultant Advisory Panel review 9/4/08. (pmo)

6/22/10 Policy Number(s) removed (amw)

4/26/11 Policy statement reworded to read: "Cryosurgical ablation is considered investigational as a treatment of benign or malignant breast tumors or for pancreatic cancer." No change in noncoverage criteria. References and rationale updated. (adn)

Policy retitled: Cryosurgical Ablation of Miscellaneous Solid Tumors Other Than Liver, Prostate, or Dermatologic Tumors

12/20/11	Policy name changed from "Cryosurgical Ablation of Solid Tumors of the Breast and Pancreas". Policy updated to include information regarding cryosurgical treatment of the lung and renal cell carcinoma. Updated "Description" section. " Medical Director review 11/23/2011. References added. (btw)
5/29/12	Specialty Matched Consultant Advisory Panel review 5/16/12. No change to policy statement. (sk)
9/18/12	Description section updated with additional information related to lung tumors. Medical Director review 9/1/12. References added. (sk)
5/28/13	Specialty Matched Consultant Advisory Panel review 5/15/13. No change to policy statement. (sk)
10/15/13	Reference added. Policy guidelines updated. Metastases added to investigational policy statement. Medical Director review 9/2013. (sk)
12/31/13	Coding update. CPT code 0340T added to Coding/Billing section. (sk)
10/28/14	Reference added. Specialty Matched Consultant Advisory Panel review 5/27/14. No change to policy statement. (sk)
12/30/14	Code 20983 added to Billing/Coding section for effective date 1/1/2015. (sk)
7/1/15	Specialty Matched Consultant Advisory Panel review 5/27/15. (sk)
9/1/15	Reference added. (sk)
7/1/16	Specialty Matched Consultant Advisory Panel review 5/25/16. (sk)
9/30/16	Reference added. Policy Guidelines updated. (sk)
6/30/17	Specialty Matched Consultant Advisory Panel review 5/31/17. (sk)
12/15/17	Reference added. Medically necessary statement added for lung cancer meeting criteria. Code 0340T deleted effective 12/31/2017. Code 32994 added effective 1/1/2018. (sk)
6/29/18	Specialty Matched Consultant Advisory Panel review 5/23/2018. The word "prostate" removed from the Policy Statement and When Not Covered section. Focal Treatments for Prostate Cancer added to list of Related Policies. (sk)
10/12/18	Reference added. Policy Guidelines updated. (sk)
7/16/19	Specialty Matched Consultant Advisory Panel review 6/28/2019. (sk)
10/15/19	Reference added. (sk)
12/31/19	CPT code 0581T added to Billing/Coding section. (sk)
6/23/20	Specialty Matched Consultant Advisory Panel review 5/20/2020. (sk)
5/18/21	Reference added. Regulatory Status updated. Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors removed from list of Related Policies. Specialty Matched Consultant Advisory Panel review 4/21/2021. (sk)
9/21/21	Reference added. Description section updated. Policy Guidelines updated. No change to policy statements. (sk)
6/14/22	Specialty Matched Consultant Advisory Panel review 4/20/2022. (sk)