

Corporate Medical Policy

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

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| Origination: | 1/2007 |
| Last CAP Review: | 12/2010 |
| Next CAP Review: | 11/2012 |
| Last Review: | 11/2011 |

Description of Procedure or Service

Cryosurgical ablation (hereafter referred to as cryosurgery) 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 carcinomas, malignant and benign breast disease, pancreatic cancer, and lung cancer has been reported in the literature.

Breast tumors: Early-stage primary breast tumors are treated surgically. The selection of lumpectomy, modified radical mastectomy, or another approach balances 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 primary 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 renal cell carcinoma (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 is almost always fatal. 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 cancer: The use of cryosurgery for the treatment of tumors of the lung is mentioned in the literature but most research has involved small numbers of patients with limited follow up. There are several ongoing clinical trials involving cryosurgery for the treatment of lung cancer.

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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. Refer to the evidence based guideline entitled, Cryosurgical Ablation of Prostate Cancer for information specific to 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;
- SeedNet System by Galil Medical; and
- Visica System by Sanarus Medical.

Related Policy:

Cryosurgical Ablation of Primary or Metastatic Liver Tumors

Related Evidence Based Guideline:

Cryosurgical Ablation 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 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, lung cancer, or other solid tumors outside the liver and prostate. 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 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 m²) and

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standard surgical approach (i.e., resection of renal tissue) is likely to substantially worsen kidney function; or

Patient is not considered a surgical candidate.

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, renal cell carcinomas in patients who are surgical candidates, pancreatic cancer, lung cancer, or other solid tumors outside the liver and prostate.

Policy Guidelines

This policy was originally created in 2003 and was updated regularly with searches of the MEDLINE database. The most recent literature search was performed for the period of April 2010 through May 2011. The literature search identified publications discussing applications of cryosurgery for primary and metastatic tumors outside the liver and prostate. All were uncontrolled case series with varied criteria to select patients for cryosurgery and reported limited data on long-term outcomes. A search of online site ClinicalTrials.gov in June 2011 found no randomized controlled trials.

The literature on the use of cryosurgical ablation of tumors addressed in this policy consists primarily of reports of single-center case series; however, evidence is accumulating that cryoablation provides short-term tumor control and perhaps survival benefit for carefully selected patients with small renal cell carcinomas. Based on the scientific data (large numbers of patients treated with follow-up) and the clinical input received, cryoablation of small (4 cm or less) renal cancers may be considered medically necessary in those patients who are not surgical candidates due to comorbid conditions or who have baseline renal insufficiency such that standard surgical procedures would impair their kidney function.

The current evidence on cryoablation for all other indications consists largely of non-comparative, case series and is insufficient to permit conclusions concerning the effect of cryoablation on health outcomes. Therefore, cryoablation is considered investigational for all other indications. Comparative studies with larger numbers of subjects and longer follow-up are needed.

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: 19105, 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.

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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 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

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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)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.