BlueCross BlueShield of Alabama

Name of Blue Advantage Policy

Cryoablation of Tumors (Excluding Liver or Prostate Tumors)

Policy #: 429
Latest Review Date: July 2024
Category: Surgery

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000, which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **cryosurgical ablation of localized renal cell carcinoma that is no more than 4 cm in size** as a **covered benefit** when performed as open, laparoscopically, or percutaneously when **either** of the following criteria is met:

- Preservation of kidney function is necessary (i.e., the individual has one kidney or renal insufficiency defined by a glomerular filtration rate [GFR] of less than 60 mL/min/m^2) and standard surgical approach (i.e., resection of renal tissue) is likely to substantially worsen kidney function; **OR**
- The individual is not considered a surgical candidate.

Blue Advantage will treat **cryosurgical ablation** as a **covered benefit** for the treatment of individuals with **osteolytic bone metastases who have failed or are poor candidates for standard treatments such as radiation and opioids**.

Blue Advantage will treat **cryosurgical ablation** to treat **lung cancer** as a **covered benefit** when **either** 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.

Blue Advantage will treat **cryosurgical ablation** as a **non-covered benefit** when used to treat any of the following (including but not limited to):

- Benign or malignant tumors of the breast, lung (other than defined above), pancreas, or bone (other than defined above)
- Other solid tumors or metastases outside the liver and prostate, including desmoid tumors
- Renal cell carcinomas in individuals who are surgical candidates

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- **Please refer to Policy #178 'MRI-Guided Focused Ultrasound (MRgFUS)' for coverage information on ultrasound ablation of the bone.**
- **Please refer to Policy #119 'Radiofrequency Ablation of Solid Tumors Excluding Liver Tumors' for radiofrequency ablation of renal, bone, and lung tumors.**
- **Please refer to NCD for Cryosurgery of Prostate (230.9)**
- **Please refer to Policy #070 'Locoregional Therapies for Hepatocellular Carcinoma and Metastatic Liver Carcinoma and Metastatic Carcinoid Tumors of the Liver' for locoregional therapies for liver tumors.**

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contracts and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is

most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

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.

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 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.

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 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 a 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.

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.

Renal Tumors

Localized renal cell carcinoma is treated with radical nephrectomy or nephron-sparing surgery. Prognosis drops precipitously if the tumor extends outside the kidney capsule because chemotherapy is relatively ineffective against metastatic renal cell carcinoma.

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.

KEY POINTS:
The most recent literature search was performed through June 3, 2024.

Summary of Evidence
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 OS, 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 OS, 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.

For individuals with NSCLC who require palliation for a central airway obstructing lesion who are treated with cryoablation, the evidence includes case series. Relevant outcomes are OS, 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 OS, 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.

Practice Guidelines and Position Statements
American College of Radiology
The American College of Radiology Appropriateness Criteria (2009, updated 2021) for post-treatment follow-up and active surveillance of renal cell carcinoma [RCC] indicated that "Ablative therapies, such as radiofrequency ablation, microwave ablation, and cryoablation, have been shown to be effective and safe alternatives [to surgical resection] for the treatment of small, localized RCCs." These recommendations are based on a review of the data and expert consensus.

American Urological Association
In 2021, the American Urological Association updated its guidelines on evaluation and management of clinically localized sporadic renal masses suspicious for renal cell carcinoma. The guideline statements on thermal ablation (radiofrequency ablation and cryoablation) are listed in Table 7.

Table 7. Guidelines on Localized Masses Suspicious for Renal Cell Carcinoma

Recommendations	LOR	LOE
Guideline statement 25		
Clinicians should consider thermal ablation (TA) as an alternate approach for the management of cT1a renal masses <3 cm in size. For patients who elect TA, a percutaneous technique is preferred over a surgical approach whenever feasible to minimize morbidity.	Moderate	C
Guideline statement 26		
Both radiofrequency ablation (RFA) and cryoablation may be offered as options for patients who elect thermal ablation	Conditional	C

Guideline statement 28		
Counseling about thermal ablation should include information regarding an increased likelihood of tumor persistence or local recurrence after primary thermal ablation relative to surgical excision, which may be addressed with repeat ablation if further intervention is elected	Strong	B

LOE: level of evidence; LOR: level of recommendation.

National Comprehensive Cancer Network
Kidney Cancer
The National Comprehensive Network (NCCN) (v.4.2024) guidelines on kidney cancer state that "thermal ablation (cryosurgery, radiofrequency ablation) is an option for the management of clinical stage T1 renal lesions. Thermal ablation is an option for clinical T1b masses in select patients not eligible for surgery. Biopsy of lesions is recommended to be done prior to or at time of ablation. Ablative techniques may require multiple treatments to achieve the same local oncologic outcomes as conventional surgery. The NCCN guidelines also note that "ablative techniques such as cryotherapy, microwave ablation, or radiofrequency ablation are alternative strategies for selected patients, particularly for those who are older, those with competing health risks and those with T1b masses not eligible for surgery." NCCN guidelines also note that "Randomized phase III comparison of ablative techniques with surgical resection (ie, radical or partial nephrectomy by open or laparoscopic techniques) has not been performed.

Non-Small Cell Lung Cancer
The NCCN (v. 5.2024) guidelines for NSCLC made the following relevant recommendations:
- Resection is the preferred local treatment modality for medically operable disease.
- Image-guided thermal ablation (IGTA) techniques include radiofrequency ablation, microwave ablation, and cryoablation.
- IGTA may be an option for select patients not receiving stereotactic ablative radiotherapy or definitive radiotherapy.
- IGTA may be considered for those patients who are deemed "high risk"- those with tumors that are for the most part surgically resectable but rendered medically inoperable due to comorbidities. In cases where IGTA is considered for high-risk or borderline operable patients, a multidisciplinary evaluation is recommended.
- IGTA is an option for the management of NSCLC lesions <3 cm. Ablation for NSCLC lesions >3 cm may be associated with higher rates of local recurrence and complications.
- The guidelines do not separate out recommendations by ablation technique and note that "each energy modality has advantages and disadvantages. Determination of energy modality to be used for ablation should take into consideration the size and location of the target tumor, risk of complication, as well as local expertise and/or operator familiarity."

Cancer Pain
The NCCN Guidelines on Adult Cancer Pain (v.2.2024) do not address cryoablation specifically for pain due to bone metastases, but note that "ablation techniques may...be helpful for pain management in patients who receive inadequate relief from pharmacological therapy.

U.S. Preventive Services Task Force Recommendations
Cryoablation/cryosurgery is not a preventive service.

KEY WORDS:
Renal cell carcinoma, RCC, cryoablation, cryosurgery, cryosurgical ablation, cryotherapy, breast cancer, pancreatic cancer, breast fibroadenoma, lung cancer, bone cancer, metastatic bone cancer, Cryocare Surgical System, CryoGen Cryosurgical System, CryoHit, SeedNet System, Visica, IceSense2, IceSense3, ablation, fibroadenoma, breast ablation, breast cryoablation, pulmonary tumors, lung cancer, cryoablation of pulmonary tumor, cryoablation of lung tumor, desmoid tumors

APPROVED BY GOVERNING BODIES:
Several cryoablation devices have been 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 (IceCure Medical);
- SeedNet™ System by Galil Medical; and
- Visica® System by Sanarus Medical.

BENEFIT APPLICATION:
Coverage is subject to member's specific benefits. Group-specific policy will supersede this policy when applicable.

CURRENT CODING:
CPT codes:

19105	Ablation, cryosurgical, of fibroadenoma, including ultrasound guidance, each fibroadenoma
19499	Unlisted procedure, breast

20983	Ablation therapy for reduction or eradication of 1 or more bone tumors (e.g., metastasis) including adjacent soft tissue when involved by tumor extension, percutaneous, including imaging guidance when performed; cryoablation
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
48999	Unlisted procedure, pancreas
50250	Ablation, open, one or more renal mass lesion(s), cryosurgical, including intra-operative ultrasound guidance and monitoring, if performed
50542	Laparoscopy, surgical; ablation of renal mass lesion(s), including intra-operative ultrasound guidance and monitoring, when performed
50593	Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy
0581T	Ablation, malignant breast tumor(s), percutaneous, cryotherapy, including imaging guidance when performed, unilateral

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POLICY HISTORY:

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Medical Policy Group, August 2018 **(4)**: Updates to Description, Key Points, and References. No change to policy statement.
Medical Policy Group, July 2019
Medical Policy Group, July 2020
Medical Policy Group, July 2021
Medical Policy Group, September 2021
Medical Policy Group, July 2022
Medical Policy Group, July 2023

UM Committee, December 2023: Policy approved by UM Committee for use for Blue Advantage business.
Medical Policy Group, July 2024
UM Committee, July 2024: Annual review of policy approved by UM Committee for use for Blue Advantage business.
