



Louisiana

Cryosurgical Ablation of Miscellaneous Solid Tumors other than Liver, Prostate, or Dermatologic Tumors

Policy # 00023

Original Effective Date: 01/26/2004

Current Effective Date: 10/01/2021

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Whole Gland Cryoablation of Prostate Cancer is addressed separately in medical policy 00022.

Note: Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors is addressed separately in medical policy 00175.

Note: Radiofrequency Ablation of Primary or Metastatic Liver Tumors is addressed separately in medical policy 00182.

Note: Cryosurgical Ablation of Primary or Metastatic Liver Tumors is addressed separately in medical policy 00220.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider cryosurgical ablation to treat localized renal cell carcinoma (RCC) to be **eligible for coverage**.**

Patient Selection Criteria

Coverage eligibility for cryosurgical ablation to treat localized renal cell carcinoma [RCC] that is no more than 4 cm in size may be considered 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 < 60 mL/min/m²), and standard

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surgical approach (ie, resection of renal tissue) is likely to worsen kidney function substantially; OR

- The patient is not considered a surgical candidate.

Based on review of available data, the Company may consider cryosurgical ablation to treat lung cancer to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for cryosurgical ablation to treat lung cancer may be considered when EITHER of the following criteria is met:

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

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers cryosurgical ablation to treat localized renal cell carcinoma (RCC) when patient selection criteria are not met to be **investigational.***

Based on review of available data, the Company considers cryosurgical ablation to treat lung cancer when patient selection criteria are not met to be **investigational.***

Based on review of available data, the Company considers cryosurgical ablation as a treatment for benign or malignant tumors of the breast, lung (other than defined above), pancreas, or bone and other solid tumors or metastases outside the liver and prostate, and to treat renal cell carcinomas in patients who are surgical candidates to be **investigational.***

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Background/Overview

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 the 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

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 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 a more advanced local disease or metastatic disease may undergo chemotherapy with radiation following resection. Treatment focuses on slowing tumor growth and palliation of symptoms.

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Renal Cell Carcinoma

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.

Cryosurgical Treatment

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

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

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 (Endocare);
- CryoGen Cryosurgical System (Cryosurgical);
- CryoHit^{®†} (Galil Medical) for the treatment of breast fibroadenoma;
- IceSense3^{™†}, ProSense^{™†}, and MultiSense Systems (IceCure Medical);
- SeedNet^{™†} System (Galil Medical); and
- Visica^{®†} System (Sanarus Medical).

FDA product code: GEH.

Rationale/Source

Cryosurgical ablation (hereafter referred to as cryosurgery or cryoablation [CRA]) 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.

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For individuals who have solid tumors (located in areas of the breast, lung, pancreas, kidney, or 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 CRA. 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). CRA 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 CRA improves outcomes for any indication better than alternative treatments. The evidence is insufficient to determine the effects of the technology on health outcomes.

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 (ie, the patient has 1 kidney or renal insufficiency defined by a glomerular filtration rate <60 mL/min/m²), and standard surgical approach (ie, 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.

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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.

Clinical input obtained in 2009 provided substantial support for CRA in patients with small renal cell cancers who were either poor surgical candidates or whose kidney function was likely to be impaired by surgery. Moreover, there was clinical support for CRA 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 included the lack of treatment alternatives and the potential for reduced harm compared with surgery.

Supplemental Information

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2017 Input

In response to requests, clinical input on use of cryosurgical ablation to manage individuals with localized renal cell cancer, use of cryosurgical ablation to manage individuals with lung cancer, and use of cryosurgical ablation to manage individuals with breast, pancreatic, or bone cancers was received from 9 respondents, including 2 specialty society-level responses, 3 physician-level responses identified by specialty societies, and 4 physicians identified by 1 health system, while this policy was under review in 2017.

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Based on the evidence and independent clinical input, the clinical input supports that the following indications provide a clinically meaningful improvement in the 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 (ie, the patient has 1 kidney or renal insufficiency defined by a glomerular filtration rate <60 mL/min/m²), and standard surgical approach (ie, 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.

Based on the evidence and independent clinical input, 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.

2009 Input

In response to requests, input was received from 2 physician specialty societies (5 reviews) and from 2 academic medical centers (3 reviews) while this policy was under review in 2009. There was strong support for the use of cryoablation in the treatment of select patients with renal tumors. There also was support for its use in the treatment of benign breast disease. Reviewers generally agreed cryoablation was investigational in the treatment of pancreatic cancer.

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Practice Guidelines and Position Statements

American College of Radiology

The American College of Radiology Appropriateness Criteria (2009) for post-treatment follow-up and active surveillance of renal cell carcinoma, updated most recently in 2019, indicated that "Ablative therapies, such as radiofrequency ablation, microwave ablation, and cryoablation, have been shown to be an effective and safe alternative [to surgical resection] for the treatment of small, localized RCCs." These recommendations are based on a review of the data and consensus.

American Urological Association

The American Urological Association (2017) updated its guidelines on the evaluation and management of clinically localized sporadic renal masses suspicious for renal cell carcinoma. The guideline statements on thermal ablation (radiofrequency ablation, cryoablation) are listed in Table 2.

Table 2. Guidelines on Localized Masses Suspicious for Renal Cell Carcinoma

Recommendations	LOR	LOE
Guideline statement 24		
Physicians 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.	Conditional	C
Guideline statement 25		
Both radiofrequency ablation and cryoablation are options for patients who elect thermal ablation	Conditional	C
Guideline statement 27		
Counseling about thermal ablation should include information regarding an increased likelihood of tumor persistence or local recurrence after primary	Strong	B

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thermal ablation relative to surgical extirpation, which may be addressed with repeat ablation if further intervention is elected		
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LOE: level of evidence; LOR: level of recommendation.

National Comprehensive Cancer Network

The NCCN (v.2.2020) guidelines on kidney cancer state that "thermal ablation (cryosurgery, radiofrequency ablation) is an option for the management of patients with clinical stage T1 renal lesions. Thermal ablation is an option for masses <3 cm, but may also be an option for larger masses in select patients. Ablation in masses >3 cm is associated with higher rates of local recurrence/persistence and complications. Biopsy of small lesions confirms a diagnosis of malignancy for surveillance, cryosurgery, and radiofrequency ablation strategies. Ablative techniques are associated with a higher local recurrence rate than conventional surgery and may require multiple treatments to achieve the same local oncologic outcomes. NCCN guidelines also note that "ablative techniques such as cryo- or radiofrequency ablation are alternative strategies for selected patients, particularly the elderly and those with competing health risks." NCCN guidelines also note that "Randomized phase III comparison with surgical resection (ie, radical or partial nephrectomy by open or laparoscopic techniques) has not been done" and "Ablative techniques are associated with a higher local recurrence rate than conventional surgery."

The NCCN (v. 5.2020) guidelines for non-small-cell lung cancer indicate surgical "resection is the preferred local treatment modality" and "other modalities include ... cryotherapy."

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 3.

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Table 3. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
<i>Renal cancer</i>			
NCT02399124 ^a	ICESECRET PROSENSE™ Cryotherapy for Renal Cell Carcinoma Trial	100	Jan 2025
NCT03390413	Robot-assisted Surgical Resection vs Cryoablation of Localised Renal Cancer - a Randomised Trial of Functional, Oncological and Financial Aspects	190	Mar 2028

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

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Policy History

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|------------|---|
| 10/21/2003 | Medical Policy Committee review |
| 01/26/2004 | Managed Care Advisory Committee approval |
| 12/07/2005 | Medical Director review |
| 12/20/2005 | Medical Policy Committee review. Format revision. FDA approval information added to policy. |
| 02/23/2006 | Quality Care Advisory Council approval |
| 10/10/2007 | Medical Director review |
| 10/17/2007 | Medical Policy Committee approval. No change to coverage eligibility. |
| 03/04/2009 | Medical Director review |

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- 03/18/2009 Medical Policy Committee approval. Changed localized renal cell carcinoma from investigational to eligible for coverage with criteria. Breast fibroadenomas removed from this policy and made into a separate policy.
- 03/05/2010 Medical Policy Committee review
- 03/19/2010 Medical Policy Implementation Committee approval. Added benign tumors of the breast to be investigational.
- 03/03/2011 Medical Policy Committee review
- 03/16/2011 Medical Policy Implementation Committee approval. Renal cell carcinomas in patients who are surgical candidates was added as investigational.
- 03/01/2012 Medical Policy Committee review
- 03/21/2012 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 03/07/2013 Medical Policy Committee review
- 03/20/2013 Medical Policy Implementation Committee approval. Title changed from “Cryosurgery Ablation of Miscellaneous Solid Tumors other than Liver or Prostate” to “Cryosurgery Ablation of Miscellaneous Solid Tumors Other than Liver or Prostate Tumors or Breast Fibroadenomas”. Removed the second criteria bullet for treatment of renal cell carcinoma requiring that the patient not be considered as a surgical candidate due to co-morbid disease. Lung cancer added to investigational statement. The investigational statement was revised for clarification.
- 03/06/2014 Medical Policy Committee review
- 03/19/2014 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
- 09/03/2015 Medical Policy Committee review
- 09/23/2015 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 09/08/2016 Medical Policy Committee review
- 09/21/2016 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes

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- 12/07/2017 Medical Policy Committee review
- 12/20/2017 Medical Policy Implementation Committee approval. Added a criteria bullet to localized renal cell carcinoma that states “the patient is not considered a surgical candidate.” Added that cryosurgical ablation to treat lung cancer may be considered eligible for coverage with criteria. Added an investigational statement for lung cancer when criteria are not met. Replaced the investigational statement regarding cryosurgical ablation for malignant tumors with an investigational statement indicating that cryosurgical ablation as a treatment for benign or malignant tumors of the breast, pancreas, or bone and other solid tumors or metastases outside the liver, prostate and breast fibroadenomas is considered to be investigational.
- 01/01/2018 Coding update
- 08/31/2018 Coding update
- 12/06/2018 Medical Policy Committee review
- 12/19/2018 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 12/05/2019 Medical Policy Committee review
- 12/11/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 05/07/2020 Medical Policy Committee review
- 05/13/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 05/06/2021 Medical Policy Committee review
- 05/12/2021 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 07/01/2021 Medical Policy Committee review
- 07/14/2021 Medical Policy Implementation Committee approval. Title changed from “Cryosurgery Ablation of Miscellaneous Solid Tumors other than Liver or Prostate Tumors or Breast Fibroadenomas” to “Cryosurgical Ablation of Miscellaneous Solid Tumors other than Liver, Prostate, or Dermatologic Tumors”. Revised the When Services May be Eligible and When Services Are Investigational sections to track BCBSA.

Next Scheduled Review Date: 07/2022

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Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)†, copyright 2020 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0581T, 19105, 20983, 32994, 50250, 50542, 50593
HCPCS	C2618
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into

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standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

****Medically Necessary (or “Medical Necessity”)** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

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