



# Louisiana

## **Cryosurgical Ablation of Primary or Metastatic Liver Tumors**

**Policy #** 00220

**Original Effective Date:** 06/20/2007

**Current Effective Date:** 07/08/2024

*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: Microwave Tumor Ablation is addressed separately in medical policy 00569.*

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

*Note: Cryosurgery Ablation of Miscellaneous Tumors other Than Liver or Prostate Tumors or Breast Fibroadenomas is addressed separately in medical policy 00023.*

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

*Note: Transcatheter Arterial Chemoembolization (TACE) to Treat Primary or Metastatic Liver Malignancies is addressed separately in medical policy 00227.*

*Note: Radioembolization for Primary and Metastatic Tumors of the Liver is addressed separately in medical policy 00110.*

## **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 (CSA) of either primary or metastatic tumors in the liver to be **investigational**.\*

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### **Background/Overview**

#### **Liver Metastases**

Hepatic tumors can be due to primary liver cancer or metastases to the liver from nonhepatic primary tumors. Primary liver cancer can arise from hepatocellular tissue (hepatocellular carcinoma [HCC]) or intrahepatic biliary ducts (cholangiocarcinoma). Multiple tumors metastasize to the liver, but there is particular interest in the treatment of hepatic metastases from colorectal cancer (CRC) given the propensity of CRC to metastasize to the liver and its high prevalence. Liver metastases from neuroendocrine tumors present a unique clinical situation. Neuroendocrine cells produce and secrete a variety of regulatory hormones (or neuropeptides), which include neurotransmitters and growth factors. Overproduction of the specific neuropeptides by cancerous cells causes various symptoms, depending on the hormone produced. In the U.S, the incidence rates of liver cancer are estimated to continually increase through 2030. Some racial groups are more affected by liver cancer than others due to differences in the prevalence of risk factors and disparities in access to quality care; the mortality rate for African Americans with HCC is higher than other racial groups in the U.S.

#### **Treatment**

Treatment of liver metastases is undertaken to reduce endocrine-related symptoms, in addition to prolonging survival and reducing symptoms related to the hepatic mass.

Surgical resection with tumor-free margins and liver transplantation are the primary treatments available that have curative potential. Many hepatic tumors are unresectable at diagnosis, due either to their anatomic location, size, the number of lesions, or underlying liver reserve. Local therapy for hepatic metastasis is indicated only when there is no extrahepatic disease, which rarely occurs for patients with primary cancers other than CRC or certain neuroendocrine malignancies. For liver metastases from CRC, postsurgical adjuvant chemotherapy has been reported to decrease recurrence rates and prolong the time to recurrence. Combined systemic and hepatic arterial chemotherapy may increase disease-free intervals for patients with hepatic metastases from CRC but apparently is not beneficial for those with unresectable hepatocellular carcinoma.

Various locoregional therapies for unresectable liver tumors have been evaluated: cryosurgical ablation (cryosurgery); radiofrequency ablation; laser ablation; transhepatic arterial embolization, chemoembolization, or radioembolization with yttrium-90 microspheres; microwave coagulation; and percutaneous ethanol injection. Cryosurgical ablation occurs in tissue that has been frozen by at

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least 3 mechanisms: (1) formation of ice crystals within cells, thereby disrupting membranes and interrupting cellular metabolism among other processes; (2) coagulation of blood, thereby interrupting blood flow to the tissue, in turn causing ischemia and apoptosis; and (3) induction of apoptosis.

Some have reported on experience with cryosurgical and other ablative methods used in combination with subtotal resection and/or procedures such as transarterial chemoembolization.

### **Procedure-Related Complications**

Cryosurgery is not a benign procedure. Treatment-related deaths occur in approximately 2% of study populations and are most often caused by cryoshock, liver failure, hemorrhage, pneumonia/sepsis, and acute myocardial infarction. Clinically significant nonfatal complication rates in the reviewed studies ranged from 0% to 83% and were generally due to the same causes as treatment-related deaths. The likelihood of complications arising from cryosurgery might be predicted, in part, by the extent of the procedure, but much of the treatment-related morbidity and mortality reflect the generally poor health status of patients with advanced hepatic disease.

## **FDA or Other Governmental Regulatory Approval**

### **U.S. Food and Drug Administration (FDA)**

Several cryosurgical devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. Use includes general surgery, urology, gynecology, oncology, neurology, dermatology, ENT [ears, nose, throat], proctology, pulmonary surgery, and thoracic surgery. The system is designed to freeze/ablate tissue by the application of extreme cold temperatures.

FDA product code: GEH.

## **Rationale/Source**

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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Cryosurgical ablation (CSA) involves the freezing of target tissues, often by inserting a probe through which coolant is circulated into the tumor. CSA can be performed as an open surgical technique or percutaneously or laparoscopically, typically with ultrasound guidance.

### Summary of Evidence

For individuals who have unresectable primary hepatocellular carcinoma (HCC) amenable to locoregional therapy who receive cryosurgical ablation (CSA), the evidence includes two meta-analyses, one randomized controlled trial (RCT), several nonrandomized comparative studies, and multiple noncomparative studies. Relevant outcomes are overall survival (OS), disease-specific survival, and treatment-related mortality and morbidity. The available RCT comparing cryoablation with radiofrequency ablation (RFA) demonstrated lower rates of local tumor progression with cryoablation but no differences in survival outcomes between groups. Although this trial provided suggestive evidence that cryoablation is comparable with RFA, trial limitations would suggest findings need to be replicated. Nonrandomized comparative studies have failed to find consistent benefit with cryoablation in outcomes related to tumor recurrence and survival. Evidence from two meta-analyses suggests equivalent OS and progression-free survival to RFA and superiority for combined transarterial chemoembolization (TACE) plus CSA over TACE alone for OS and tumor progression. Additional randomized comparative evidence is needed to permit conclusions about the effectiveness of cryoablation compared with other locoregional therapies. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have unresectable liver metastases from neuroendocrine tumors amenable to locoregional therapy who receive CSA, the evidence includes a Cochrane review and case series. Relevant outcomes are OS, disease-specific survival, symptoms, and treatment-related mortality and morbidity. The available evidence base is very limited. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have unresectable liver metastases from colorectal cancer amenable to locoregional therapy who have CSA, the evidence includes an RCT, several nonrandomized comparative and noncomparative studies, and systematic reviews of these studies. Relevant outcomes are OS, disease-specific survival, and treatment-related mortality and morbidity. The available RCT comparing surgical resection with cryoablation was judged as high risk of bias. Some nonrandomized comparative studies have reported improved survival outcomes for patients managed with cryotherapy compared with those managed with resection alone; however, these

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studies were subject to bias in the selection of patients for treatments. Additional controlled studies are needed to permit conclusions about the effectiveness of cryoablation compared with other locoregional therapies. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

### **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.

In response to requests, input was received from 2 physician specialty societies and 3 academic medical centers while this policy was under review in 2008. All reviewers supported the use of cryoablation for liver tumors and, in general, cited the studies reviewed in the Rationale section. Some reviewers considered cryoablation as 1 of several ablative techniques that could be used in these patients.

#### **Practice Guidelines and Position Statements**

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

#### **National Comprehensive Cancer Network**

The National Comprehensive Cancer Network (NCCN) indicates that ablative techniques may be used in the treatment of certain hepatic tumors. The NCCN guidelines on hepatocellular carcinoma (v. 1.2023) include cryoablation in a list of ablative techniques, along with radiofrequency ablation (RFA), percutaneous alcohol ablation, and microwave ablation; however, the literature cited in the guidelines reports on only RFA and ethanol ablation. For hepatocellular carcinoma, the NCCN makes the following category 2A recommendation:

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"All patients with HCC [hepatocellular carcinoma] should be evaluated for potential curative therapies (resection, transplantation, and for small lesions, ablative strategies). Locoregional therapy should be considered in patients who are not candidates for surgical curative treatments, or as a part of a strategy to bridge patients for other curative therapies.

Ablation (radiofrequency, cryoablation, percutaneous alcohol injection, microwave):

- All tumors should be amenable to ablation such that the tumor and, in the case of thermal ablation, a margin of normal tissue is treated. A margin is not expected following percutaneous ethanol injection.
- Tumors should be in a location accessible for percutaneous/laparoscopic/open approaches for ablation.
- Caution should be exercised when ablating lesions near major vessels, major bile ducts, diaphragm, and other intra-abdominal organs.
- Ablation alone may be curative in treating tumors  $\leq 3$  cm. In well-selected patients with small properly located tumors, ablation should be considered as definitive treatment in the context of a multidisciplinary review. Lesions 3 to 5 cm may be treated to prolong survival using arterially directed therapies, or with combination of an arterially directed therapy and ablation as long as tumor location is accessible for ablation.
- Unresectable/inoperable lesions  $> 5$  cm should be considered for treatment using arterially directed or systemic therapy.
- Currently, no adjuvant therapies have been shown to have added value post-ablation."

For intrahepatic cholangiocarcinoma (isolated intrahepatic mass), the guidelines recommend locoregional therapy using arterially directed therapies or external-beam radiotherapy.

The NCCN guidelines on neuroendocrine and adrenal tumors (v.1. 2023) address the use of hepatic-directed therapies for patients with unresectable hepatic-predominant progressive metastatic neuroendocrine tumors. These guidelines support consideration of ablative therapies such as RFA or cryoablation if near-complete tumor burden can be achieved (category 2B recommendation).

For ablative therapy, the NCCN makes the following category 2B recommendation:

"Percutaneous thermal ablation, often using microwave energy (radiofrequency and cryoablation are also acceptable), can be considered for oligometastatic liver disease, generally up to four lesions

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each smaller than 3 cm. Feasibility considerations include safe percutaneous imaging-guided approach to the target lesions, and proximity to vessels, bile ducts, or adjacent non-target structures that may require hydro- or aero-dissection for displacement."

The NCCN guidelines on the treatment of colon cancer with liver metastases (v. 2. 2023) consider patients with liver oligometastases as candidates for tumor ablation therapy. Ablative techniques include RFA, microwave ablation, cryoablation, percutaneous ethanol injection, and electro-coagulation. Use of surgery, ablation, or the combination "with the goal of less-than-complete resection/ablation of all known sites of disease, is not recommended other than in the scope of a clinical trial" (category 2A recommendations).

**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 unpublished trials that might influence this review are listed in Table 1.

**Table 1. Summary of Key Trials**

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT04724226	Cryoablation Combined With Camrelizumab and Apatinib in Advanced Hepatocellular Carcinoma (C-couple)	34	Aug 2024
NCT05897268	Cryoablation Combined With Tislelizumab Plus Lenvatinib in 1L Treatment of Advanced HCC (CASTLE-10) (CASTLE-10)	25	Dec 2025

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NCT05057845	Cryoablation Combined With Tislelizumab Plus Lenvatinib as Second-line or Later Therapy in Advanced Hepatocellular Carcinoma	25	Sep 2024
NCT05303038	Cryoablation Combined With Tixelizumab and Bevacizumab in Liver Metastatic TNBC Patients Failed by Multiline Therapy (Castle06(BC))	15	April 2024
NCT05057052	Cryoablation Combined With Sintilimab Plus Regorafenib In Previously Treated Colorectal Cancer Liver Metastasis	25	Sep 2024
NCT05622825	Valuation of the Safety and Efficacy of Combination of Cryoablation and Dendritic Cell/ Cytokine-induced Killers Cells Treatment for Advanced Liver Cancers	15	Dec 2024

NCT: national clinical trial.

<sup>a</sup> Denotes industry-sponsored or cosponsored trial.

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- 06/13/2007 Medical Director review
- 06/20/2007 Medical Policy Committee approval
- 06/04/2009 Medical Director review
- 06/17/2009 Medical Policy Committee approval
- 06/03/2010 Medical Policy Committee approval.
- 06/16/2010 Medical Policy Implementation Committee approval. No change to coverage.

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06/02/2011	Medical Policy Committee approval.
06/15/2011	Medical Policy Implementation Committee approval. No change to coverage.
06/14/2012	Medical Policy Committee review
06/20/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/06/2013	Medical Policy Committee review
06/25/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/05/2014	Medical Policy Committee review
06/18/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/04/2015	Medical Policy Committee review
06/20/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
06/02/2016	Medical Policy Committee review
06/20/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
06/01/2017	Medical Policy Committee review
06/21/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/07/2018	Medical Policy Committee review
06/20/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/06/2019	Medical Policy Committee review
06/19/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/04/2020	Medical Policy Committee review
06/10/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/03/2021	Medical Policy Committee review

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- 06/09/2021 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 06/02/2022 Medical Policy Committee review
- 06/08/2022 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 06/01/2023 Medical Policy Committee review
- 06/14/2023 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 06/06/2024 Medical Policy Committee review
- 06/12/2024 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 06/2025

### 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 2023 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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# Louisiana

## Cryosurgical Ablation of Primary or Metastatic Liver Tumors

Policy # 00220

Original Effective Date: 06/20/2007

Current Effective Date: 07/08/2024

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	47371, 47381, 47383, 76940
HCPCS	No codes
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 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 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.

‡ Indicated trademarks are the registered trademarks of their respective owners.

**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.

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**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.

**NOTICE:** Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

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