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## Medical Policy



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**Joint Medical Policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information.**

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**Category: Surgery**

**\*Current Policy Effective Date: 3/1/07**

**Title: Cryosurgical Ablation (Cryotherapy) of Unresectable Hepatic Tumors**      **Procedure Code(s): 47371, 47381**

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### Description/Background

Cryosurgical ablation involves the freezing of target tissues by inserting a probe or probes into the tissue. The probe then circulates a coolant into the targeted tissue. The coolant may be liquid nitrogen or argon gas, which cools tissue by rapid expansion in the probe tip area. Cells in the target tissue are killed by a variety of mechanisms including protein denaturation, cell membrane rupture, cell dehydration and/or ischemia. Cryosurgical ablation of the tumor can be done close to blood vessels without fear of hemorrhage. The procedure may be performed laparoscopically as well as through an open procedure. It usually requires only an outpatient stay.

Presently, surgical resection with adequate margins and liver transplantation are the only two treatments available which have been demonstrated to be potentially curative for a significant percentage (25-40%) of patients with hepatic tumors. Without treatment, the 5-year survival rate for these patients approaches zero. Cryosurgical ablation may be used alone or as an adjunct to surgical resection of the tumor in addition to chemotherapy and radiation to treat hepatocellular carcinoma (HCC).

In Michigan in 1999, according to CDC data, there were 8.1 reported cases per 100,000 population of invasive primary liver and intrahepatic bile duct carcinoma. There were 62.5 reported cases of colorectal cancer (CRC) per 100,000 population in Michigan the same year. On average 15-25% of CRC patients develop unresectable liver metastases.

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(\*See policy history boxes for any previous effective dates, if applicable)

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Cryosurgical Ablation (Cryotherapy) of Unresectable Hepatic Tumors.NP.ps.030107.RET

**CPT/HCPCS Level II Codes and Description** *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

**Established codes:**

47371 Laparoscopy, surgical, ablation of one or more liver tumor(s); cryosurgical  
47381 Ablation, open, of one or more liver tumor(s); cryosurgical  
76490 Ultrasound guidance for, and monitoring of, tissue ablation

**Other codes (investigational, not medically necessary, etc.):**

N/A

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**Diagnoses/Medical Conditions**

- Malignant neoplasm of liver and intrahepatic bile ducts; Liver, primary
  - Secondary malignant neoplasm of respiratory and digestive systems; Liver, specified as secondary
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**Medical Policy Statement**

The safety and effectiveness of cryosurgical ablation of unresectable hepatic tumors have been established. It may be considered a useful therapeutic alternative for patients with unresectable hepatocellular carcinoma, colorectal, or other cancer metastases confined to the liver when 1-2 lesions are present measuring 3-4 cm in size or less.

**Rationale**

Cryosurgical ablation of unresectable hepatic tumors is considered an effective treatment as adjunct therapy for primary hepatocellular carcinoma when a total surgical resection is contraindicated. It is also useful for select secondary colorectal metastases confined to the liver.

Cryosurgical ablation of unresectable hepatic tumors is considered an effective therapy as an adjunct to surgical resection for primary hepatocellular carcinoma in the following circumstances:

- When conventional surgical resection is contraindicated.
  - It is useful for selected secondary colorectal metastases confined to the liver.
  - When there are  $\leq 4$  lesions scattered in multiple segments of the liver.
  - When lesions are near major hepatic vessels so that a standard surgical margin would not be possible.
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- For those patients with limited hepatic reserve who are unable to tolerate removal of large amounts of liver tissue.

Recent advances in ultrasound (US) technology allow real-time intraoperative imaging. The new argon cryogen probes freeze faster and colder than the older liquid nitrogen probes and can be stopped instantaneously to avoid damage to surrounding tissue. The temperature of the probe is monitored continuously.

### **Medical Policy Position Summary (Non-clinical summary statement for customer use)**

Cryosurgery (cryotherapy) is a technique for freezing and killing abnormal cells by using extreme cold produced by liquid nitrogen (or argon gas). It can be used as an alternative to surgery for liver cancer. For these tumors liquid nitrogen or argon gas is circulated through a hollow instrument called a cryoprobe, which is placed in contact with the tumor. Ultrasound or magnetic resonance imaging is used to guide the probe and monitor the freezing of the cells, thus limiting damage to nearby healthy tissue. After cryosurgery the frozen tissue thaws and is either naturally absorbed by the body. Cryosurgery has been established either to be used alone or as an adjunct to resection of the tumor, chemotherapy and radiation in the treatment of liver tumors.

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### **Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)**

Cryosurgery treatment of certain selected primary and secondary liver tumors is considered effective under the following conditions:

- The lesions are  $\leq 2$  in number
- They are  $\leq 4$  cm in size
- They are related to unresectable hepatocellular carcinoma, colorectal carcinoma or other metastases confined to the liver

Primary carcinomas of breast, lung, stomach, pancreas, adenocarcinoma of unknown origin and other primary cancers which are widely disseminated at the same time liver metastases are present are not appropriate for cryosurgical ablation.

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### **Related Policies**

- Yttrium-90 Microsphere Therapy (TheraSphere®; SIR-Spheres®)
- Radiofrequency Ablation of Unresectable Hepatic Tumors

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### **Medicare Information**

There is no National Medicare ruling on this subject. There is a Local CMS Region V Policy "Cryosurgery for liver Tumors" latest revision date 9/1/2005.

Cryosurgery in the treatment of certain selected primary and secondary liver tumors is considered safe and effective in the following clinical scenarios:

- Primary hepatocellular carcinoma when conventional surgical resection is felt to be contraindicated or when cryosurgical ablation is used as an adjunct to surgical resection; and
- Carcinoma metastatic to the liver,
- The cryosurgical device used must be FDA approved for the indications used.

In the case of carcinomas metastatic to the liver, the following qualifying conditions for coverage must be met:

- The primary cancer site must be effectively controlled;
- The metastatic lesions must be limited to the liver and not present in other organs;
- The open laparotomy approach must be used;
- The patient must have no more than 3 liver metastases, except in rare instances (such as multiple neuroendocrine liver metastases).
- No lesion should be larger than 7 cm. in size.

Note:

Primary carcinomas of the breast, lung, stomach, pancreas, adenocarcinoma of unknown origin and other primary cancers which are widely disseminated at the same time liver metastases are present are not appropriate for cryosurgical ablation.

*(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicaid Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)*

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## References

- Bilchik, A, MD, PhD, Wood, MD, et al. "Cryosurgical Ablation and Radiofrequency Ablation for Unresectable Hepatic Malignant Neoplasms *A Proposed Algorithm*" © Archives of Surgery Vol 135 June 2000 657-664.
- Blue Cross Blue Shield Association, "Radiofrequency or Cryoablation of Liver Tumors" #7.01.75, *Medical Policy Reference Manual*, Issue 1:2006, Original Policy Date 12/15/00, Last Review Date 03/07/06.
- Blue Cross Blue Shield Association "Cryosurgical Ablation of Unresectable Hepatic Tumors" *Technology Assessment Program*, Volume 15, No. 14 November 2000.
- CDC Cancer Prevention and Control <http://www.cdc.gov/cancer/CancerBurden/mi.htm>
- Goering, John D., et al, "Cryoablation and liver resection for non-colorectal liver metastases," Excerpta Medical, *The American Journal of Surgery*, Vol. 183, 2002.
- *HAYES Medical Technology Directory*, "Cryosurgery for Primary and Metastatic Cancers of the Liver" Lansdale PA., HAYES, Inc., November 18, 2005.
- Wisconsin Physicians Service (WPS), "Cryosurgery for Liver Tumors," *WPS Local Medical Review Policy* GSURG-033, original Michigan effective date, 11/05/1997, most recent Michigan revision date 09/01/2005.

*The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through October 23, 2006, the date the research was completed.*

**Joint BCBSM/BCN Medical Policy History**

<b>Policy Effective Date</b>	<b>BCBSM Signature Date</b>	<b>BCN Signature Date</b>	<b>Comments</b>
7/21/03	7/21/03	7/7/03	Joint policy established
3/1/07	1/3/07	10/23/07	Routine maintenance; policy retired

Next Review: This is an established policy and no longer subject to periodic review

**Pre-Consolidation Medical Policy History**

<b>Original Policy Date</b>		<b>Comments</b>
BCN	N/A	Revised: N/A
BCBSM	1/24/01	Revised: N/A

# Blue Care Network

## POLICY: CRYOSURGICAL ABLATION (CRYOTHERAPY) OF UNRESECTABLE HEPATIC TUMORS

### **I. Coverage Determination:**

Cryosurgical ablation (cryotherapy) for unresectable hepatic tumors is a covered benefit for all BCN members who meet the appropriate patient selection criteria.

### **II. Benefit Information:**

Cryosurgical ablation of unresectable hepatic tumors considered a benefit if the lesions are:

- Less than or equal to 2 in number,
- Less than or equal to 4 cm in size, and
- Classified as unresectable hepatocellular carcinoma, colorectal carcinoma or other metastases confined to the liver.

### **III. Benefit Exclusions:**

Cryosurgical ablation (cryotherapy) for unresectable hepatic tumors is an exclusion for all diagnoses other than 155.0 and 197.7.

Cryosurgical ablation of the liver is contraindicated for the following primary carcinomas (not in remission) at the same time liver metastases are present:

- Breast
- Lung
- Stomach
- Pancreas
- Adenocarcinoma of unknown origin
- Other primary cancers which are widely disseminated

### **IV. Administrative Guidelines:**

- The member's contract must be active at the time the service is rendered.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Appropriate copayments will apply
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.
- Payment is based on BCN payment rules, individual certificate benefits and certificate riders.

### **V. Effective Date:**

Policy updated: 3/1/07  
Joint policy effective date: 7/21/03