

Corporate Medical Policy

Cryosurgical Ablation of Primary or Metastatic Liver Tumors

File Name: cryosurgical_ablation_of_primary_or_metastatic_liver_tumors
Origination: 8/2010
Last CAP Review: 6/2019
Next CAP Review: 5/2020
Last Review: 6/2019

Description of Procedure or Service

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

Hepatic tumors can arise 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 carcinoma (CRC) given the propensity of CRC to metastasize to the liver and the prevalence of CRC. 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.

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 or 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, 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 colorectal carcinoma or certain neuroendocrine malignancies. For liver metastases from colorectal cancer, post-surgical adjuvant chemotherapy has been reported to decrease recurrence rates and prolong time to recurrence. Combined systemic and hepatic arterial chemotherapy may increase disease-free intervals for patients with hepatic metastases from colorectal cancer, 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; trans-hepatic 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 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 cell death; and 3) induction of apoptosis (cell death).

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Recent studies including a small randomized controlled trial and case series have reported experience with cryosurgical and other ablative methods used in combination with subtotal resection and/or procedures such as TACE (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.

Regulatory Status

Several cryosurgical devices have clearance by the U.S Food and Drug Administration (FDA). For example, the ENDOcare™ Cryocare System (Endocare, Irvine, CA) was cleared for marketing through the 510 (k) process in December 1996 for “use in general surgery, dermatology, neurology, thoracic surgery, ENT [ears, nose throat], gynecology, oncology, proctology and urology for the ablation of tissue, including liver metastases, skin lesions, warts, and removal of prostate tissue.”

Related Policies:

Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors

Chemoembolization of the Hepatic Artery, Transcatheter Approach

Radioembolization for Primary and Metastatic Tumors of the Liver

Microwave Tumor Ablation

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

*****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

Cryosurgical Ablation of Primary or Metastatic Liver Tumors is considered investigational for all applications. 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 Primary or Metastatic Liver Tumors is covered

Not applicable.

When Cryosurgical Ablation of Primary or Metastatic Liver Tumors is not covered

Cryosurgical ablation of either primary or metastatic tumors in the liver is considered investigational.

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Policy Guidelines

For individuals who have unresectable primary hepatocellular carcinoma amenable to locoregional therapy who receive cryosurgical ablation, the evidence includes one randomized controlled trial (RCT), several nonrandomized comparative studies, and multiple noncomparative studies. Relevant outcomes are overall survival, disease-specific survival, and treatment-related morbidity and mortality. The available RCT comparing cryoablation and radiofrequency ablation (RFA) demonstrated lower rates of local tumor progression with cryoablation, but no differences in survival outcomes between groups. Although this study provided suggestive evidence that cryoablation is comparable to RFA, the study has several limitations that suggest findings need to be replicated. Additional comparative evidence is needed to allow conclusions about the effectiveness of cryoablation compared with other locoregional therapies. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have unresectable liver metastases from neuroendocrine tumors amenable to locoregional therapy who receive cryosurgical ablation, the evidence includes a Cochrane review and case series. Relevant outcomes are overall survival, disease-specific survival, symptoms, and treatment-related morbidity and mortality. The available evidence base is very limited. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have unresectable liver metastases from colorectal cancer amenable to locoregional therapy who receive cryosurgical ablation, the evidence includes one RCT, a number of nonrandomized comparative studies and noncomparative studies, and systematic reviews of these studies. Relevant outcomes are overall survival, disease-specific survival, and treatment-related morbidity and mortality. The available RCT comparing surgical resection with cryoablation was judged to be at high risk of bias. Some nonrandomized comparative studies reported improved survival outcomes for patients managed with cryotherapy compared with those managed with resection alone; however, these studies were subject to bias in the selection of patients for treatments. Additional controlled studies are needed to allow conclusions about the effectiveness of cryoablation compared with other locoregional therapies. The evidence is insufficient to determine the effects of the technology on health outcomes.

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.bcsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 47371, 47381, 47383, 76940

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.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.75, 3/2010

Medical Director Review - 7/2010

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.75, 3/10/2011

Cryosurgical Ablation of Primary or Metastatic Liver Tumors

Specialty Matched Consultant Advisory Panel - 8/2011

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.75, 12/8/2011

Medical Director - 3/2012

Specialty Matched Consultant Advisory Panel 5/2012

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.75, 12/13/2012

Specialty Matched Consultant Advisory Panel 5/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.75, 12/12/2013

Specialty Matched Consultant Advisory Panel 5/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.75, 12/11/2014

Specialty Matched Consultant Advisory Panel 5/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.75, 12/10/2015

Specialty Matched Consultant Advisory Panel 5/2016

Specialty Matched Consultant Advisory Panel 5/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.75, 6/8/2017

Specialty Matched Consultant Advisory Panel 5/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.75, 7/12/2018

Specialty Matched Consultant Advisory Panel 6/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.75, 9/12/2019

Policy Implementation/Update Information

8/17/10 New policy. Cryosurgical ablation of either primary or metastatic tumors in the liver is investigational. Reviewed with Medical Director 7/21/2010. Notice given 8/31/2010. Policy effective 12/7/2010. (btw)

5/24/11 "Policy" statement reformatted for consistency, no change to policy intent. References added. (btw)

10/1/11 Specialty Matched Consultant Advisory Panel review August 31, 2011. No change to policy. (btw)

4/17/12 Policy Guidelines revised. Reference added. Medical Director review 3/21/2012. (btw)

5/29/12 Specialty Matched Consultant Advisory Panel review 5/16/12. No change to policy. (sk)

1/29/13 Related policies added. Reference added. No change to policy statement. (sk)

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- 5/28/13 Specialty Matched Consultant Advisory Panel review 5/15/13. No change to policy. (sk)
- 4/1/14 Reference added. No change to Policy statement. (sk)
- 6/10/14 Specialty Matched Consultant Advisory Panel review 5/27/14. No change to policy. (sk)
- 12/30/14 Added code 47383 to Billing/Coding section for effective date 1/1/2015. (sk)
- 2/24/15 Reference added. (sk)
- 7/1/15 Specialty Matched Consultant Advisory Panel review 5/27/15. (sk)
- 4/1/16 Reference added. Description section reorganized. Policy Guidelines updated. (sk)
- 7/1/16 Specialty Matched Consultant Advisory Panel review 5/25/16. (sk)
- 6/30/17 Specialty Matched Consultant Advisory Panel review 5/31/2017. (sk)
- 7/28/17 Reference added. Policy Guidelines updated. (sk)
- 6/29/18 Specialty Matched Consultant Advisory Panel review 5/23/2018. (sk)
- 10/12/18 Reference added. Policy Guidelines updated. (sk)
- 7/16/19 Specialty Matched Consultant Advisory Panel review 6/28/2019. (sk)
- 10/29/19 Reference added. (sk)

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.