BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 7.01.75 Cryosurgical Ablation of Primary or Metastatic Liver Tumors

Annual Effective Policy Date: January 1, 2026

Original Policy Date: December 2011

Related Policies:

7.01.13 - Surgical Treatment of Bilateral Gynecomastia
7.01.91 - Radiofrequency Ablation of Primary or Metastatic Liver Tumors
7.01.92 - Cryoablation of Tumors Located in the Kidney, Lung, Breast, Pancreas, or Bone
7.01.95 - Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors
8.01.11 - Transcatheter Arterial Chemoembolization to Treat Primary or Metastatic Liver Malignancies
8.01.43 - Radioembolization for Primary and Metastatic Tumors of the Liver

Cryosurgical Ablation of Primary or Metastatic Liver Tumors

Description

Description

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.

OBJECTIVE

The objective of this evidence review is to determine whether cryoablation improves the net health outcome in individuals with unresectable primary and metastatic liver tumors amenable to locoregional therapy.

POLICY STATEMENT

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

POLICY GUIDELINES

None

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

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

Summary of Evidence

For individuals who have unresectable primary hepatocellular carcinoma (HCC) amenable to locoregional therapy who receive cryosurgical ablation (CSA), the evidence includes 2 meta-analyses, a 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 the 2 meta-analyses which included RCTs 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 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

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.1.2025) 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.[36,] For hepatocellular carcinoma, the NCCN makes the following category 2A recommendation:

"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 (microwave/radiofrequency, surgical, or percutaneous ethanol injection :

- 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 ≤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, systemic therapy, or RT [radiation therapy]."

The NCCN guidelines on biliary tract cancer (v.2.2025)[37,] recommend that patients with intrahepatic cholangiocarcinoma should be evaluated for potentially curative therapies such as ablation, arterially directed therapies, and RT. Specific recommendations for ablation include (category 2A recommendation):

- "All tumors should be amenable to complete ablation so that the tumor and a margin of normal tissue up to 1 cm can be treated."
- "For small single tumors <3 cm, whether recurrent or primary, thermal ablation is a reasonable alternative to surgical resection, particularly in patients with high-risk disease."
- "Options for ablation include cryoablation, radiofrequency ablation, microwave ablation, and irreversible electroporation."

The NCCN guidelines on neuroendocrine and adrenal tumors (v.2.2025) address the use of hepatic-directed therapies for patients with unresectable hepatic-predominant progressive metastatic neuroendocrine tumors.[38,] 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 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.4.2025) consider patients with liver oligometastases as candidates for tumor ablation therapy.[39,] 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.

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
December 2011	New policy	
June 2012	Replace policy	Policy statement changed from investigational to not medically necessary. Related policies added.
March 2013	Replace policy	Policy updated with literature search; references 4, 11, 12, 15 added. Policy statement unchanged.
March 2014	Replace policy	Policy updated with literature review; references added, reordered or removed. Policy statement unchanged.
March 2015	Replace policy	Policy updated with literature review; reference 2 added. Policy statement unchanged.
March 2017	Replace policy	Policy updated with literature review through November 17, 2015; references 3-4 and 8 added. Policy statement unchanged except "not medically necessary, corrected to "investigational, due to FDA 510(k) clearance.
September 2018	Replace policy	Policy updated with literature search through May 7, 2018; no references added. Policy statement unchanged.
December 2019	Replace policy	Policy updated with literature search through July 7, 2019; no references added. Policy statement unchanged.
December 2020	Replace policy	Policy updated with literature review through July 28, 2020; no references added. Policy statement unchanged.
December 2021	Replace policy	Policy updated with literature review through July 28, 2021; references added. Policy statement unchanged.
December 2022	Replace policy	Policy updated with literature review through July 25, 2022; references added; guidelines updated. Policy statement unchanged.
December 2023	Replace policy	Policy updated with literature review through August 3, 2023; references added; guidelines updated. Policy statement unchanged.
December 2024	Replace policy	Policy updated with literature review through July 31, 2024; no references added; guidelines updated. Policy statement unchanged.
December 2025	Replace policy	Policy updated with literature review through July 29, 2025; reference added; guidelines updated. Policy statement unchanged.