

MEDICAL POLICY

POLICY TITLE	RADIOFREQUENCY ABLATION OF PRIMARY OR METASTATIC LIVER TUMORS
POLICY NUMBER	MP 1.055

CLINICAL BENEFIT	<input type="checkbox"/> MINIMIZE SAFETY RISK OR CONCERN. <input type="checkbox"/> MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. <input type="checkbox"/> ASSURE APPROPRIATE LEVEL OF CARE. <input type="checkbox"/> ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. <input checked="" type="checkbox"/> ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. <input type="checkbox"/> ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	11/1/2024

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I. POLICY

Radiofrequency ablation of primary, inoperable (e.g., due to location of lesion[s] and/or comorbid conditions), hepatocellular carcinoma may be considered **medically necessary** under the following conditions:

- As a primary treatment of hepatocellular carcinoma meeting the Milan criteria (a single tumor of less than or equal to 5 cm or up to 3 nodules less than 3 cm)
- As a bridge to transplant, where the intent is to prevent further tumor growth and to maintain an individual’s candidacy for liver transplant.

Radiofrequency ablation as a primary treatment of inoperable hepatic metastases may be considered **medically necessary** under the following conditions:

- Metastases are of colorectal origin and meet the Milan criteria (a single tumor of less than or equal to 5 cm or up to 3 nodules less than 3 cm)
- Metastases are of neuroendocrine in origin and systemic therapy has failed to control symptoms.

Radiofrequency ablation of primary, inoperable, hepatocellular carcinoma is considered **investigational** under the following conditions:

- When there are more than 3 nodules or when not all sites of tumor foci can be adequately treated.
- When used to downstage (downsize) hepatocellular carcinoma in individuals being considered for liver transplant.

Radiofrequency ablation of primary, operable hepatocellular carcinoma is **investigational**.

Radiofrequency ablation for hepatic metastasis is considered **investigational** for:

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- Hepatic metastases from colorectal cancer or neuroendocrine tumors that do not meet the criteria above; and
- For hepatic metastases from other types of cancer except colorectal cancer or neuroendocrine tumors.

There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure for the above indications.

The National Comprehensive Cancer Network (NCCN) is a nonprofit alliance of cancer centers throughout the United States. NCCN develops the Clinical Practice Guidelines in Oncology which are recommendations aimed to help health care professionals diagnose, treat, and manage patients with cancer. Guidelines evolve continuously as new treatments and diagnostics emerge and may be used by Capital Blue Cross when determining medical necessity according to this policy.

Cross-references:

MP 1.088 Cryosurgical Ablation of Miscellaneous Solid Tumors other than Liver, Prostate, or Dermatologic Tumors

MP 1.121 Cryosurgical Ablation of Primary or Metastatic Liver Tumors

MP 1.084 Radiofrequency Ablation of Miscellaneous Solid Tumors, Excluding Liver Tumors

II. PRODUCT VARIATIONS

This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: <https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies>

III. DESCRIPTION/BACKGROUND

Radiofrequency ablation (RFA) is a procedure in which a probe is inserted into the center of a tumor and heated locally by a high frequency, alternating current that flows from electrodes. The local heat treats the tissue adjacent to the probe, resulting in a 3- to 5-cm sphere of dead tissue. The cells killed by RFA are not removed but are gradually replaced by fibrosis and scar tissue. If there is local recurrence, it occurs at the edge and, in some cases, may be retreated. RFA may be performed percutaneously, laparoscopically, or as an open procedure.

Hepatic and Neuroendocrine Tumors

Hepatic tumors can arise as primary liver cancer (hepatocellular cancer) or by metastasis to the liver from other tissues. Local therapy for hepatic metastasis may be indicated when there is no

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extrahepatic disease, which rarely occurs for patients with primary cancers other than colorectal carcinoma or certain neuroendocrine malignancies.

Neuroendocrine tumors are tumors of cells that possess secretory granules and originate from the neuroectoderm. Neuroendocrine cells have roles both in the endocrine system and in the nervous system. They produce and secrete a variety of regulatory hormones, or neuropeptides, which include neurotransmitters and growth factors. Overproduction of the specific neuropeptides produced by the cancerous cells causes various symptoms, depending on the hormone produced. They are rare, with an incidence of 2 to 4 per 100000 per year.

Treatment

Treatment options for hepatocellular carcinoma (HCC) range from potentially curative treatments, such as resection or liver transplantation, to nonsurgical options, which include ablative therapies (radiofrequency ablation [RFA], cryoablation, microwave ablation, percutaneous ethanol, or acetic acid injection), transarterial embolization, radiation therapy, and systemic therapy. Choice of therapy depends on the severity of the underlying liver disease, size, and distribution of tumors, vascular supply, and patient overall health. Treatment of liver metastases is undertaken to prolong survival and to reduce endocrine-related symptoms and hepatic mass-related symptoms.

At present, surgical resection with adequate margins or liver transplantation constitutes the only treatments available with demonstrated curative potential for hepatic tumors. However, most hepatic tumors are unresectable at diagnosis, due either to their anatomic location, size, number of lesions, or underlying liver reserve. Patients may also have comorbid conditions and do not qualify for surgical resection. Milan criteria can aid in determining eligibility for transplantation. Milan criteria include single tumor <5 cm, no more than 3 foci with each not exceeding 3 cm, absence of angioinvasion, and absence of extrahepatic involvement. Patients with resectable HCC are also potentially eligible for a liver transplant. However, the availability of liver donors limits its use.

Radiofrequency Ablation

RFA is a procedure in which a needle electrode is inserted into a tumor either percutaneously, through a laparoscope, or through an open incision. The electrode is heated by a high-frequency, alternating current, which destroys tissue in a 3 to 5 cm sphere of the electrode. RFA has been investigated as a treatment for unresectable hepatic tumors, both as a primary intervention and as a bridge to liver transplant. In the latter setting, RFA is being tested to determine whether it can reduce the incidence of tumor progression in patients awaiting transplantation and thus maintain patients' candidacy for liver ablation, transhepatic arterial chemoembolization, microwave coagulation, percutaneous ethanol injection, and radioembolization (yttrium-90 microspheres). Hepatic resection, liver transplantation (in carefully selected individuals), and radiofrequency ablation have a 5-year survival of >50% and are considered curative.

The National Comprehensive Cancer Network (NCCN)

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The NCCN clinical practice guidelines for hepatocellular carcinoma (V1.2023) states the following with Category 2A recommendations in the Principles of Locoregional Therapy-Ablation section:

- 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.
- 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 less than or equal to 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 greater than 5 cm should be considered for treatment using arterially directed therapy, systemic therapy, or EBRT.

Tumor Ablation Resection is the standard approach for the local treatment of resectable metastatic colon cancer. However, patients with liver or lung oligometastases can also be considered for tumor ablation therapy, particularly in cases that may not be optimal for resection. Ablative techniques include radiofrequency ablation (RFA, microwave ablation (MWA), cryoablation, and electro-coagulation (irreversible electroporation). Per the NCCN, there is extensive evidence on the use of RFA as a reasonable treatment option for non-surgical candidates and for recurrent disease after hepatectomy with small liver metastases that can be treated with clear margins. Ablative techniques may be considered alone or in conjunction with resection. All original sites of disease need to be amenable to ablation or resection.

IV. RATIONALE

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SUMMARY OF EVIDENCE

Primary, Operable Hepatocellular Carcinoma

For individuals who have primary, operable hepatocellular carcinoma (HCC) who receive RFA, the evidence includes randomized controlled trials (RCTs), meta-analyses RCTs and retrospective observational studies, and additional observational studies. Relevant outcomes are overall survival (OS), disease-specific survival, change in disease status, and morbid events. The majority of data found that patients undergoing surgical resection experienced longer survival outcomes and lower recurrence rates than patients receiving RFA, though complication rates were higher with surgical resection. Results from observational studies have

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suggested that RFA alone or RFA plus PEI could be as effective as a resection for small HCC tumors as OS and DFS rates were not significantly different between RFA and surgical resection. Although the exact size cutoff has not been established, current National Comprehensive Cancer Network guidelines suggest use of ablation as a treatment option when tumors are 3 cm or smaller. Some studies found that OS was similar in patients receiving RFA or resection when tumor size was 3 cm or less; however, OS was significantly longer in patients undergoing resection if the tumor size was between 3.1 cm and 5 cm. Further study in a multicenter RCT would permit greater certainty whether RFA, with or without other ablative or arterial directed therapies, is as effective as surgical resection in treating HCC tumors 3 cm or smaller. The evidence is insufficient to determine the effects of the technology RFA on health outcomes.

Inoperable Hepatocellular Carcinoma

For individuals who have inoperable HCC who receive RFA, the evidence includes randomized trials and several systematic reviews and meta-analyses. Relevant outcomes are OS, disease-specific survival, change in disease status, and morbid events. Surgical resection of HCC, compared with RFA, has shown superior survival, supporting the use of RFA for unresectable HCC and for those who are not candidates for surgical resection. Response rates have demonstrated that, in patients with small foci of HCC (less than or equal to 3 lesions), RFA appears to be better than ethanol injection in achieving complete ablation and preventing local recurrence. Three-year survival rates of 80% have been reported. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Inoperable Hepatocellular Carcinoma Awaiting Liver Transplant

For individuals who have inoperable HCC awaiting liver transplant who receive RFA, the evidence includes small case series. Relevant outcomes are OS, disease-specific survival, and change in disease status. A number of approaches are used in this patient population, including RFA and other locoregional therapies, particularly transarterial chemoembolization. Locoregional therapy has reduced the dropout rate of patients with HCC awaiting a liver transplant. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Inoperable Hepatic Metastases of Colorectal Origin

For individuals who have inoperable hepatic metastases of colorectal origin who receive RFA, the evidence includes an RCT, systematic reviews and meta-analyses, prospective cohort series, and retrospective case series. Relevant outcomes are OS, disease-specific survival, symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. There are no RCTs comparing RFA with alternative treatments for patients with unresectable colorectal liver metastases. However, an RCT assessing RFA combined with chemotherapy found improved survival at 8 years compared with chemotherapy alone. In addition, prospective studies have demonstrated that OS following RFA is at least equivalent to and likely better than that for currently accepted systemic chemotherapy in well-matched patients with unresectable hepatic metastatic colorectal cancer who do not have extrahepatic

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disease. Results from a number of uncontrolled case series also have suggested RFA of hepatic colorectal cancer metastases produces long-term survival that is at minimum equivalent to but likely superior to historical outcomes achieved with systemic chemotherapy. Evidence from a comparative study has indicated RFA has fewer deleterious effects on quality of life than chemotherapy and that RFA patients recover quality of life significantly faster than chemotherapy recipients. It should be noted that patients treated with RFA in different series might have had better prognoses than those who had chemotherapy, suggesting patient selection bias might at least partially explain the better outcomes observed following RFA. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Inoperable Hepatic Metastases of Neuroendocrine Origin

For individuals who have inoperable hepatic metastases of neuroendocrine origin who receive RFA, the evidence includes case series and a systematic review of case series. Relevant outcomes are OS, disease-specific survival, symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. Most reports of RFA treatment for neuroendocrine liver metastases have assessed small numbers of patients or subsets of patients in reports of multiple ablative methods or very small subsets of larger case series of patients with various diagnoses. The available evidence has indicated that durable tumor and symptom control of neuroendocrine liver metastases can be achieved using RFA in individuals whose symptoms are not controlled by systemic therapy or who are ineligible for resection. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Hepatic Metastases Not of Colorectal or Neuroendocrine Origin

For individuals who have hepatic metastases, not of colorectal or neuroendocrine origin who receive RFA, the evidence includes small nonrandomized comparative studies and small case series. Relevant outcomes are OS, disease-specific survival, symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. Similar to primary HCC, resection appears to have the most favorable outcomes. For patients who are ineligible for resection, RFA may provide a survival benefit. However, the evidence is limited by study designs with a high-risk of bias and small sample sizes. The evidence is insufficient to determine the effects of the technology RFA on health outcomes.

V. DEFINITIONS

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DENATURATION refers to a change in conditions (temperature, addition of a substance) that causes irreversible change in a protein's structure, usually resulting in precipitation of the protein.

EXTRAHEPATIC refers to outside or unrelated to the liver.

HEPATIC pertains to the liver.

HYPERTHERMIA refers to the use of microwave or radiofrequency energy to increase body temperature.

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METASTASIS is the movement of body cells (esp. cancer cells) from one part of the body to another.

NEUROENDOCRINE MALIGNANCIES refer to a diverse group of tumors, such as carcinoid, islet cell tumors, neuroblastoma, and small-cell carcinomas of the lung.

PERCUTANEOUS refers to that which is passed or effected through the skin.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

Procedure Codes							
47370	47380	47382					

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ICD-10-CM Diagnosis Code	Description
C22.0	Liver cell carcinoma
C22.9	Malignant neoplasm of liver, not specified as primary or secondary
C78.7	Secondary malignant neoplasm of liver and intrahepatic bile duct
C7B.02	Secondary carcinoid tumors of liver

IX. REFERENCES

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MEDICAL POLICY

POLICY TITLE	RADIOFREQUENCY ABLATION OF PRIMARY OR METASTATIC LIVER TUMORS
POLICY NUMBER	MP 1.055

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X. POLICY HISTORY

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MP 1.055	CAC 10/29/02
	CAC 2/22/05
	CAC 3/28/06
	CAC 3/27/07
	CAC 11/27/07
	CAC 11/25/08
	CAC 9/29/09 Consensus Review
	CAC 4/26/11 Adopt BCBSA. Extracted information regarding cryosurgical ablation and created a separate policy titled Cryosurgical Ablation of Primary or metastatic

MEDICAL POLICY

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	Liver Tumors 1.121. Changed cryosurgical ablation policy statement from medically necessary to investigational. Treatment of Hepatocellular Cancer (HCC) coverage indication was modified to include those patients who cannot undergo a curative procedure and have no more than 3 nodules. Coverage also expanded to include use as a bridge to transplant and selective use in metastatic neuroendocrine tumors.
	CAC 6/26/12 Consensus. FEP variation changed to reference FEP Medical Policy Manual MP-7.01.91. No change to policy statements.
	7/24/13 Admin coding review complete
	CAC 9/24/13 Consensus. No change to policy statements. Added Rationale section. References updated. Guidelines moved out of Background/Description into Policy Guidelines section.
	CAC 11/25/14 Consensus. No change to policy statements. References and rationale updated. Codes reviewed, no changes
	CAC 11/24/15 Consensus review. No change to the policy statements. Reference and rationale update. Coding updated.
	CAC 11/29/16 Consensus review. No change to the policy statements. Reference and rationale update. Coding updated. Variation reformatting.
	CAC 1/30/18 Minor revision. Policy statements edited for clarity and specificity, including the distinction between operable and non-operable tumors and the Milan criteria. Statement added that RFA for operable HCC is considered investigational. Cross-Reference, Description/Background, Rationale and Reference sections updated. Coding Updated
	1/25/19 Consensus review. No change to the policy statements. Rationale condensed and References updated.
	2/12/20 Consensus review. No change to policy statements. Coding reviewed.
	1/4/21 Consensus review. No change to policy statement. Update to references and background.
	08/19/2022 Consensus review. No change to policy statement. Added NCCN statement to policy and NCCN recommendations to background. Added information about the Milan criteria. Updated references.
	08/07/2023 Consensus review. No change to policy statement. Updated background and references.
	1/19/2024 Administrative update. Clinical benefit added.

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