MASSACHUSETTS

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Medical Policy

Radiofrequency Ablation of Primary or Metastatic Liver Tumors

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Policy Number: 286

BCBSA Reference Number: 7.01.91 (For Plans internal use only)
NCD/LCD: NA

Related Policies

- Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors, #259
- Radioembolization for Primary and Metastatic Tumors of the Liver, #292
- Cryosurgical Ablation of Primary or Metastatic Liver Tumors, #633
- Transcatheter Arterial Chemoembolization (TACE) to Treat Primary or Metastatic Liver Malignancies, #634

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue℠ and Medicare PPO Blue℠ Members

Radiofrequency ablation of primary, inoperable (eg, 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 ≤5 cm or up to 3 nodules <3 cm).
- As a bridge to transplant, where the intent is to prevent further tumor growth and to maintain a 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 ≤5 cm or up to 3 nodules <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:

- 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.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is **not required**.
Commercial PPO and Indemnity	Prior authorization is **not required**.
Medicare HMO Blue℠	Prior authorization is **not required**.
Medicare PPO Blue℠	Prior authorization is **not required**.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

CPT codes:	Code Description
47370	Laparoscopy, surgical, ablation of one or more liver tumor(s); radiofrequency
47380	Ablation, open, of one or more liver tumor(s); radiofrequency
47382	Ablation, 1 or more liver tumor(s), percutaneous, radiofrequency

Description

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 extrahepatic disease, which rarely occurs for patients with primary cancers other than colorectal carcinoma or certain neuroendocrine malignancies. A study from 2016 determined that the incidence of liver cancer was higher among White individuals, Black individuals, and Hispanic individuals born after 1938.[1] The incidence of hepatocellular carcinoma was twice as high for US-born Hispanic men compared to Hispanic men born outside of the US. This may be due to the increased risk of smoking, hepatitis B or C infection, and diabetes among US-born Hispanic individuals.

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 100,000 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 chemoembolization, 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 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. Comorbid conditions may also make patients unqualified for surgical resection.

Radiofrequency Ablation

Radiofrequency ablation 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. The cells killed by RFA are not removed but are gradually replaced by fibrosis and scar tissue. If there is a local recurrence, it occurs at the edge of the treated tissue and, in some cases, is retreated. Radiofrequency ablation has been investigated as a treatment for unresectable hepatic tumors, both as a primary intervention and as a bridge to a 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).

Note that RFA of extrahepatic tumors is addressed policy #259

Summary

Description

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 a local recurrence, it occurs at the edge of the treated tissue and, in some cases, is retreated. Radiofrequency ablation may be performed percutaneously, laparoscopically, or as an open procedure.

Summary of Evidence

For individuals who have primary, operable hepatocellular carcinoma (HCC) who receive radiofrequency ablation (RFA), the evidence includes meta-analyses of randomized controlled trials (RCTs) and/or retrospective observational studies, an RCT, 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. Some meta-analyses and an RCT of specifically selected populations (eg, small tumor sizes or Child-Pugh Class A liver function or HCC within the Milan criteria) found that OS and disease-free survival (DFS) rates were not significantly different between RFA and surgical resection. Results from observational studies have suggested that RFA alone or RFA plus percutaneous ethanol injection (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. An exact tumor cutoff size has not been established. 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 that the technology results in an improvement in the net health outcome.

For individuals who have inoperable HCC who receive RFA, the evidence includes RCTs and several systematic reviews and meta-analyses. Relevant outcomes are OS, disease-specific survival, change in disease status, and morbid events. When resection is not an option, nonsurgical options include RFA, PEI, transarterial chemoembolization (TACE), cryoablation, microwave ablation, and systemic therapy. Meta-analyses comparing RFA to other local ablative therapies have found that RFA and microwave ablation are similarly effective, that RFA is more effective than PEI, and that RFA may be better than cryoablation. The evidence comparing RFA with TACE is limited, and no conclusions can be drawn. RFA has also been shown to improve survival in patients with unresectable HCC as an adjunct to chemotherapy. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

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 TACE. 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 an improvement in the net health outcome.

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 who have unresectable colorectal liver metastases. However, an RCT assessing RFA plus 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 currently accepted systemic chemotherapy in well-matched patients with unresectable hepatic metastatic colorectal cancer (CRC) who do not have extrahepatic disease. Results from a number of uncontrolled case series also have suggested RFA of hepatic CRC metastases produces long-term survival that is at a 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 their 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 an improvement in the net health outcome.

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 an improvement in the net health outcome.

For individuals who have hepatic metastases, not of colorectal or neuroendocrine origin who receive RFA, the evidence includes a systematic review, 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 that the technology results in an improvement in the net health outcome.

Policy History

Date	Action
9/2024	Annual policy review. Policy updated with literature review through May 20, 2024; references added. Policy statements unchanged.
8/2023	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
9/2022	Annual policy review. Reference added and additional references updated. Minor editorial refinements to policy statements; intent unchanged.
8/2021	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
9/2020	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
9/2019	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
9/2018	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
1/2018	Annual policy review. Policy statements reformatted and edited for clarity and specificity, including the distinction between operable and non-operable tumors and the Milan criteria. The intent of the statements is unchanged. A statement has been added that RFA for operable HCC is considered investigational. Clarified coding information.
10/2016	Annual policy review. New references added.
11/2015	Annual policy review. New references added.
9/2014	Annual policy review. New references added.
6/2014	Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.
11/2013	Removed ICD diagnosis code 155.2 as it does not meet the intent of the policy.
10/2013	Annual policy review. New references added.
11/2011-4/2012	Medical policy ICD10 remediation: Formatting, editing and coding updates. No changes to policy statements.
7/2011	Reviewed - Medical Policy Group – Hematology and Oncology. No changes to policy statements.
3/2011	New policy describing covered and non-covered indications. Effective 3/2011.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:
Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

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