



MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 04/30/13
LAST REVIEW DATE: 08/13/14
LAST CRITERIA REVISION DATE: 08/13/14
ARCHIVE DATE:

RADIOFREQUENCY ABLATION OF PRIMARY OR METASTATIC LIVER TUMORS

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

Radiofrequency Ablation:

In radiofrequency ablation (RFA), a probe is inserted into the center of a tumor and the noninsulated electrodes, which are shaped like prongs, are projected into the tumor; heat is generated locally by a high frequency, alternating current that flows from the 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.

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Criteria

All requests for treatment of hepatocellular carcinoma with radiofrequency ablation will be reviewed by the medical director(s) and/or clinical advisor(s).

- Radiofrequency ablation for the treatment of primary malignant hepatic lesions is considered **medically necessary** with documentation of **ALL** of the following:
 1. No more than 3 nodules
 2. All tumor foci can be adequately treated
 3. Surgical resection not feasible
 4. Transplantation not feasible (unless radiofrequency ablation is used as a bridge to transplant)
 5. Tumor size is 5 cm or less
 6. Lab values normal
 - INR, and
 - PT, and
 - PTT, and
 - Platelet count
- Radiofrequency ablation for the treatment of metastatic malignant hepatic lesions from colorectal cancer in the absence of extrahepatic metastatic disease is considered **medically necessary** with documentation of **ALL** of the following:
 1. All tumor foci can be adequately treated
 2. Surgical resection not feasible
 3. Tumor size is 5 cm or less
 4. Lab values normal
 - INR, and
 - PT, and
 - PTT, and
 - Platelet count

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Criteria: (cont.)

All requests for treatment of hepatocellular carcinoma with radiofrequency ablation will be reviewed by the medical director(s) and/or clinical advisor(s).

- Radiofrequency ablation for the treatment of metastatic malignant hepatic lesions from neuroendocrine tumors in symptomatic individuals is considered **medically necessary** with documentation of **ALL** of the following:
 1. Surgical resection not feasible
 2. Systemic therapy has failed to control symptoms
- Radiofrequency ablation as a bridge to transplantation is considered **medically necessary** with documentation of **ALL** of the following:
 1. Primary hepatocellular carcinoma confined to the liver (no metastases)
 2. Intent is to prevent progression of liver tumor
 3. Currently listed as a candidate for liver transplantation
- Radiofrequency ablation for all other indications not previously listed or if above criteria not met is considered **experimental or investigational** based upon:
 1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome, and
 3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

These indications include, *but are not limited to*:

- Treatment of primary hepatocellular carcinoma when all sites of tumor foci cannot be adequately treated
- Treatment of primary hepatocellular carcinoma when there are more than 3 nodules



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Resources:

Resources published prior to 04/30/13 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. 7.01.91 BCBS Association Medical Policy Reference Manual. Radiofrequency Ablation of Primary or Metastatic Liver Tumors. Re-issue date 07/10/2014, issue date 12/15/2000.