The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Preauthorization is required. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

Description

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.

Background

Hepatic tumors can arise either as primary liver cancer (hepatocellular cancer [HCC]) 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. At present, surgical resection with adequate margins or liver transplantation constitutes the only treatments available with demonstrated curative potential. However, the majority of hepatic tumors are unresectable at diagnosis, due either to their anatomic location, size, number of lesions, or underlying liver reserve.

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 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 a variety of symptoms depending on the hormone produced. They are rare, with an incidence of two to four per 100,000 per year. Treatment of liver metastases is undertaken to prolong survival and reduce endocrine-related symptoms, as well as symptoms related to the hepatic mass.

Radiofrequency ablation (RFA) has been investigated as a treatment for unresectable hepatic tumors, both as primary treatment and as a bridge to liver transplant. In the latter setting, it is hoped that RFA will reduce the incidence of tumor progression while awaiting transplantation and thus maintain a patient’s candidacy for liver transplant during the wait time for a donor organ. This issue has become less problematic with additional priority now assigned for patients with stage T2 hepatocellular cancer (HCC).

Various locoregional therapies for unresectable liver tumors have been investigated: RFA, cryosurgical ablation (cryosurgery), laser ablation, trans-hepatic artery embolization/chemoembolization (TACE), microwave coagulation, percutaneous ethanol injection, and radioembolization (Yttrium-90 microspheres).

Radiofrequency ablation of extrahepatic tumors is addressed in a separate Protocol.
Radiofrequency Ablation of Primary or Metastatic Liver Tumors

Related Protocols:
- Cryosurgical Ablation of Primary or Metastatic Liver Tumors
- Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors
- Transcatheter Arterial Chemoembolization (TACE) to Treat Primary or Metastatic Liver Malignancies
- Radioembolization for Primary and Metastatic Tumors of the Liver

Corporate Medical Guideline

Radiofrequency ablation of primary hepatocellular carcinoma (HCC) may be considered medically necessary as a primary treatment of HCC for patients when there are no more than three nodules and all tumor foci can be adequately treated (see Policy Guidelines).

Radiofrequency ablation of primary hepatocellular carcinoma (HCC) is considered medically necessary as a bridge to transplant, where the intent is to prevent further tumor growth and to maintain a patient’s candidacy for liver transplant.

Radiofrequency ablation of primary hepatocellular carcinoma (HCC) is considered investigational when there are more than three nodules or when not all sites of tumor foci can be adequately treated.

Radiofrequency ablation of primary hepatocellular carcinoma (HCC) is considered investigational when used to downstage (downsize) hepatocellular carcinoma (HCC) in patients being considered for liver transplant.

Radiofrequency ablation may be considered medically necessary as a primary treatment of hepatic metastases 5 cm or less in diameter from colorectal cancer in the absence of extrahepatic metastatic disease when all tumor foci can be adequately treated (see Policy Guidelines).

Radiofrequency ablation may be considered medically necessary as treatment of hepatic metastases from neuroendocrine tumors in patients with symptomatic disease when systemic therapy has failed to control symptoms (see Policy Guidelines).

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 with the exception of colorectal or neuroendocrine tumors.

Policy Guideline

Explicit criteria have not been established for radiofrequency ablation (RFA) of hepatocellular cancer (HCC) or cancer metastasis to the liver.

For the medically necessary indications noted above for RFA in those with primary HCC and metastatic colorectal or neuroendocrine tumors, patients should not be candidates for curative resections (e.g., due to location of lesion(s) and/or comorbid conditions) and for HCC should also not be candidates for liver transplantation.

Candidacy for RFA treatment of HCC is based on several factors that include number of tumor foci (nodules), size of tumor foci, and accessibility. In general, the randomized trials for HCC have included patients with three or fewer hepatic lesions measuring 5 cm or less (and often 3 cm or less) using current technology.

Candidacy for RFA treatment of metastatic colorectal cancer is based on several factors that include number of tumor foci, size of tumor foci, and accessibility. In general, published studies with metastatic colorectal cancer
have included patients with four-five or fewer hepatic lesions measuring 5 cm or less using current technology.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.


44. Pawlik TM, Vauthey JN, Abdalla EK et al. Results of a single-center experience with resection and ablation for sarcoma metastatic to the liver. Arch Surg 2006; 141(6):537-44.