MEDICAL POLICY

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SUBJECT: RADIOFREQUENCY TUMOR ABLATION	**EFFECTIVE DATE: 10/18/01** **REVISED DATE: 07/18/02, 05/21/03, 05/19/04, 05/18/05, 02/16/06, 12/21/06, 12/20/07, 12/18/08, 11/19/09, 11/18/10, 12/15/11, 11/15/12, 10/17/13, 09/18/14, 08/20/15, 07/21/16, 07/20/17, 07/19/18**
POLICY NUMBER: 7.01.32 **CATEGORY: Technology Assessment**	**PAGE: 1 OF: 10**

- ***If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.***
- ***If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.***
- ***If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.***

POLICY STATEMENT:

I. Based upon our criteria and assessment of peer-reviewed literature, radiofrequency ablation of malignant *hepatic lesions* (primary and metastatic) is considered a **medically appropriate** treatment option for selected patients meeting ALL of the following conditions:
   A. The patient has no evidence of uncontrolled extrahepatic systemic metastatic disease;
   B. The lesions(s) treated by radiofrequency are not amenable to open surgical resection or the patient is considered at high risk for adverse outcomes (morbidity and mortality) during open surgical resection; and
   C. The lesion size is 5 cm or less.

II. Based upon our criteria and assessment of peer-reviewed literature, radiofrequency ablation as a bridge to transplant is a **medically appropriate** treatment option in patients with *hepatocellular carcinoma* who meet liver transplant criteria and are waiting liver transplantation.

III. Based upon our criteria and assessment of peer-reviewed literature, percutaneous radiofrequency ablation of an *osteoid osteoma* is a **medically appropriate** alternative to surgical excision for patients with ALL of the following indications:
   A. The patient can not be managed successfully with medical management;
   B. There is sufficient clinical and imaging evidence that tumor is osteoid osteoma; and
   C. The tumor location allows for safe placement of the radiofrequency catheter (e.g., at least 1 cm away from vascular, neural or other anatomic structures which have the potential for damage,)

IV. Based upon our criteria and assessment of peer-reviewed literature, radiofrequency ablation of *renal tumors* is considered a **medically appropriate** treatment option in the following circumstances:
   A. Patients with a solitary kidney; OR
   B. Patients with a contraindication to surgery (e.g., significant comorbidities location or number of tumors preclude surgical intervention); AND
   C. Tumor size is equal to or less than 4 cm.

   The comorbidities of patients unable to undergo surgery should not be so severe as to limit their life expectancy to less than one year.

V. Based upon our criteria and assessment of peer-reviewed literature, radiofrequency ablation is considered **medically appropriate** when utilized for palliation of pain in patients with *osteolytic bone metastases* who have failed or are poor candidates for standard treatments such as opioids or radiation.

VI. Based upon our criteria and assessment of peer-reviewed literature, radiofrequency ablation has been medically proven effective and therefore is considered **medically appropriate** to treat an *isolated peripheral non-small cell lung cancer lesion* that is no more than 3 cm in size when the following criteria are met:
   A. Surgical resection or radiation treatment with curative intent is considered appropriate based on stage of disease, however, medical co-morbidity renders the individual unfit for those interventions; AND
   B. Tumor is located at least 1 cm from the trachea, main bronchi, esophagus, aorta, aortic arch branches, pulmonary artery and the heart.

VII. Based upon our criteria and assessment of peer-reviewed literature, radiofrequency ablation has been medically proven effective and therefore is considered **medically appropriate** to treat *malignant non-pulmonary tumor(s) metastatic to the lung* that are no more than 3 cm in size when ALL the following criteria are met:
   A. The patient is not considered a surgical candidate or radiofrequency ablation is being performed in order to preserve lung function when surgical resection or radiation treatment is likely to substantially worsen pulmonary status; AND
   B. There is no evidence of extrapulmonary metastases; AND
   C. The tumor is located at least 1 cm from the trachea, main bronchi, esophagus, aorta, aortic arch branches, pulmonary artery and the heart; AND
   D. There are no more than 3 tumors per lung to be ablated; AND
   E. Tumors are amenable to complete ablation; AND
   F. Twelve months have elapsed since the last ablation.

VIII. Based upon our criteria and assessment of peer-reviewed literature, radiofrequency ablation has not been medically proven to be effective and is considered **investigational** as a treatment method for *other solid tumors*, including, but not limited to pancreatic, thyroid, breast tumors and uterine fibroid tumors.

Refer to Corporate Medical Policy # 7.01.36 regarding Transurethral Radiofrequency Needle Ablation of the Prostate for Benign Prostatic Hyperplasia.

Refer to Corporate Medical Policy # 7.02.03 regarding Cryosurgical Tumor Ablations.

Refer to Corporate Medical Policy # 7.02.07 regarding Liver Transplantation.

Refer to Corporate Medical Policy # 7.01.69 regarding Selective Internal Radiation Therapy (SIRT).

Refer to Corporate Medical Policy # 7.01.78 regarding Peptide Receptor Radionuclide Therapy.

Refer to Corporate Medical Policy # 11.01.03 regarding Experimental and Investigational Services.

POLICY GUIDELINES:

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

Radiofrequency is an ablative technique that relies on heat to effect tumor killing. A radiofrequency electrode is passed into a tumor under sonographic, CT or MR-guidance. In radiofrequency ablation (RFA), tumors are destroyed in situ by thermal coagulation and protein denaturation. High frequency alternating current flows from un-insulated electrode tips into surrounding tissue. As the tissue ions attempt to follow the change in the direction of the alternating current, ionic agitation results in frictional heating. The tissue surrounding the electrode, rather than the electrode itself, is the primary source of heat. It is presumed that tissue heating drives extracellular and intracellular water out of the tissue, resulting in coagulative necrosis. RFA is usually used to treat inoperable tumors or to treat patients who are ineligible for surgery due to advanced age or co-morbidities. RFA was developed initially to treat inoperable tumors of the liver. RFA is now being proposed as a minimally invasive treatment alternative for other solid tumors such as breast, pancreas, pulmonary renal and bone.

Radiofrequency ablation can be administered by open surgery, laparoscopic surgery or percutaneously.

RATIONALE:

Radiofrequency ablation of liver tumors is not subject to FDA approval. However, several devices/probes used to ablate tumors have received FDA marketing clearance. Current studies have demonstrated that RFA is most effective (causes tissue necrosis) in the treatment of small lesions confined to the liver. Studies of RFA of small liver tumors have provided

similar outcomes in terms of local recurrence and overall survival for patients with unresectable hepatic malignancy compared to alternative therapies such as percutaneous ethanol injection (PEI).

Overall, most studies of RFA for miscellaneous malignant solid tumors (other than liver) consist of case studies, which have reported only short-term outcomes such as tumor response and immediate tumor control. These studies have not determined RFA's effect on the overall survival and net health benefit of these patients compared to the well established local and systemic treatments currently available for these tumors. More rigorous scientific reviews, long-term follow-up and randomized prospective trials are needed to help better define the role of RFA in oncology.

Renal tumors

The majority of studies were small case series of individual institution experiences with this treatment modality. Patients in these case series had small renal tumors and were unsuitable for surgical management (e.g., severe co-morbidities, a solitary kidney, or multiple renal tumors). Outcomes of these case series have demonstrated that RFA for renal cell carcinoma is a promising treatment and creates tumor necrosis, but longer-term outcomes are needed to determine if RFA provides a durable survival benefit. RFA as an alternative to surgical intervention requires comparative studies to determine if it provides a similar survival benefit.

Lung tumors

In summary, while the available studies are limited by study design, accumulating evidence from case series suggests that RFA may be a treatment option in selected patients with primary, non-small cell lung cancer and metastatic pulmonary tumors. Evidence suggests RFA may have survival rates and have rates of procedure-related complications and mortality similar to surgery. Surgical resection remains the treatment of choice, but in patients unable to tolerate surgery due to medical comorbidities, RFA may be considered a treatment option.

The December 2010 guidance from National Institute for Clinical Excellence (NICE) states: "Current evidence on the efficacy of percutaneous radiofrequency ablation (RFA) for primary or secondary lung cancers is adequate in terms of tumor control. There is a small incidence of complications, specifically pneumothorax, which may have serious implications for these patients with already compromised respiratory reserve. This procedure may be used provided that normal arrangements are in place for clinical governance, consent and audit. Patient selection for percutaneous RFA for primary or secondary lung cancers should be carried out by a multidisciplinary team, which will usually include a thoracic surgeon, an oncologist and a radiologist. This procedure should only be carried out by radiologists who regularly undertake image guided interventional procedures…"

The 2011 National Comprehensive Cancer Network (NCCN) Practice Guideline on NSCLC states RFA may be an option for node-negative patients who either refuse surgery or cannot tolerate surgery because of poor performance status, significant cardiovascular risk, poor pulmonary function, and/or comorbidities.

Transplant Setting

The drop out rates of patients with hepatocellular carcinoma from liver transplant lists have been reported to range from 20-40% due to tumor progression. Recent studies utilizing radiofrequency ablation as a bridge to transplant have increased days on the transplant list considerably and decreased dropout rates to 12-15%.

The evidence related to the use of RFA in patients with HCC to specifically downsize/downgrade tumors to meet priority transplant criteria is insufficient at this time due to inconsistent outcomes reported in the literature. Data related to tumor recurrence in this patient population requires longer-term follow-up.

Osteoid Osteomas

Studies investigating the efficacy of radiofrequency ablation for osteoid osteomas provide evidence that RFA provides comparable outcomes to surgical excision in regards to tumor destruction and pain relief and allows for a decrease in hospital stay and quicker postoperative recovery. RFA treatment of osteoid osteoma is not appropriate for large lesions or for lesions whose location make it technically difficult to perform percutaneously.

Breast Tumors

There is insufficient evidence in the literature related to the effectiveness of RFA in the treatment of patients with breast cancer. The outcome data from current clinical trials is inconsistent and no conclusions can be drawn on the effect of RFA on recurrence or disease-free survival rates. Studies are also limited by small sample populations, short-term follow-up and a lack of comparative studies with already established breast conserving therapies.

Bone Metastases

The majority of literature consists of uncontrolled studies with only a limited number of cases. However, the patient populations comprised individuals with limited or no treatment options, for whom short-term pain relief is an appropriate outcome.

Thyroid Tumors

The evidence for RFA in thyroid tumors is primarily limited to case series and uncontrolled studies. While RFA has been shown to reduce thyroid tumor volume and improve clinical symptoms, complications can be common and available evidence is insufficient to determine the impact of RFA on net health outcomes.

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

CPT:	20982	Ablation therapy for reduction or eradiation of 1 or more bone tumors (e.g., metastasis) including adjacent soft tissue when involved by tumor extension, percutaneous, including imaging guidance when performed; radiofrequency
	32998	Ablation therapy for reduction or eradication of one or more pulmonary tumor(s) including pleura or chest wall when involved by tumor extension, percutaneous, radiofrequency, unilateral
	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, one or more liver tumor(s), percutaneous, radiofrequency
	50592	Ablation, one or more renal tumor(s), percutaneous, unilateral, radiofrequency
	58674 **(E/I)**	Laparoscopy, surgical, ablation of uterine fibroid(s), including intraoperative ultrasound guidance and monitoring, radiofrequency ~~effective 1/1/2017~~
	76940	Ultrasound guidance for, and monitoring of, parenchymal tissue ablation
	77013	Computerized axial tomographic guidance for, and monitoring of, parenchymal tissue ablation
	77022	Magnetic resonance guidance for, and monitoring of, parenchymal tissue ablation
	0404T **(E/I)**	Transcervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency

HCPCS: No specific code(s)

ICD10:	C22.0-C22.9	Malignancies of liver (code range)
	C34.90-C34.92	Malignant neoplasm of unspecified part of bronchus or lung (code range)
	C64.1-C64.9	Malignant neoplasm kidney, except renal pelvis (code range)
	C65.1- C65.9	Malignant neoplasm renal pelvis (code range)
	C66.1-C66.9	Malignant neoplasm ureter (code range)
	C78.7	Secondary malignant neoplasm of liver and intrahepatic bile duct
	D16.00-D16.8	Benign neoplasm bones (code range)
	D16.9	Benign neoplasm bone and articular cartilage, unspecified
	Investigational diagnosis codes:	
	174.0-174.9	Malignant neoplasm of female breast (code range)
	218.0-218.9	Uterine leiomyoma (code range)
	610.2	Fibroadenosis of breast
	C50.011-C50.919	Malignant neoplasm of breast (code range)
	D25.0-D25.9	Leiomyoma of uterus (code range)
	N60.21-N60.29	Fibroadenosis of breast (code range)

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KEY WORDS:

Radiofrequency ablation.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based on our review, there is no specific regional or national coverage determination for Radiofrequency Tumor Ablation.