MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Radiofrequency Tumor Ablation**
Policy Number	**7.01.32**
Category	**Technology Assessment**
Original Effective Date	**10/18/01**
Committee Approval Date	**10/18/01, 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, 07/18/19, 08/20/20, 08/19/21, 06/16/22, 06/22/23, 06/20/24**
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Archive Review Date	**N/A**
Product Disclaimer	• *Services are contract dependent; 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 or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) 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.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, radiofrequency ablation of malignant hepatic lesions (primary and metastatic) is considered a **medically appropriate** treatment option for selected patients when **ALL** of the following criteria are met:

   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;
   C. The lesion size is five (5) cm or less.

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

III. Based upon our criteria and assessment of the peer-reviewed literature, percutaneous radiofrequency ablation of an osteoid osteoma is considered a **medically appropriate** alternative to surgical excision when **ALL** of the following criteria are met:

   A. The patient can not be managed successfully with medical management;
   B. There is sufficient clinical and imaging evidence that the patient's tumor is osteoid osteoma;
   C. The tumor location allows for safe placement of the radiofrequency catheter (e.g., at least one (1) cm away from vascular, neural or other anatomic structures that have the potential for damage).

IV. Based upon our criteria and assessment of the peer-reviewed literature, radiofrequency ablation of renal tumors is considered a **medically appropriate** treatment when the following criteria are met:

A. The patient has a solitary kidney; **OR**
B. Surgery is contraindicated for the patients (e.g., significant comorbidities or location or number of tumors preclude surgical intervention);
AND
C. Tumor size is equal to or less than (4) four cm.

The comorbidities of patients unable to undergo surgery should not be so severe as to limit their life expectancy to less than one (1) year.

V. Based upon our criteria and assessment of the 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 the peer-reviewed literature, radiofrequency ablation has been medically proven to be effective and, therefore, is considered **medically appropriate** to treat an isolated peripheral non-small cell lung cancer lesion that is no more than three (3) cm in size, when **BOTH** of 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 one (1) cm from the trachea, main bronchi, esophagus, aorta, aortic arch branches, pulmonary artery and heart.

VII. Based upon our criteria and assessment of the peer-reviewed literature, radiofrequency ablation has been medically proven to be effective and, therefore, is considered **medically appropriate** to treat malignant non-pulmonary tumor(s) metastatic to the lung that are no more than three (3) cm in size, when **ALL** the of 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;
B. There is no evidence of extrapulmonary metastases;
C. The tumor is located at least one (1) cm from the trachea, main bronchi, esophagus, aorta, aortic arch branches, pulmonary artery and heart;
D. There are no more than three (3) tumors per lung to be ablated;
E. Tumors are amenable to complete ablation;
F. Twelve months have elapsed since the last ablation.

VIII. Based upon our criteria and assessment of peer reviewed literature, laparoscopic, transcervical ultrasound-guided radiofrequency ablation (e.g., the Acessa System, Sonata Device) in premenopausa*l* woman 18 years or older, has been medically proven to be effective and, therefore, is considered **medically appropriate** as an alternative to hysterectomy or myomectomy for the treatment of uterine fibroid tumors, when the member has persistence of **ONE OR MORE** of the following symptoms directly attributed to uterine fibroids:

A. Excessive menstrual bleeding (menorrhagia),
B. Pelvic pain or pressure as a direct result of the fibroid;
C. Gastrointestinal symptoms related to compression of the bowel (e.g., constipation, bloating) as a direct result of the fibroid.
D. Urinary symptoms related to compression of the ureter or bladder (e.g., urinary frequency, urgency)
E. Dyspareunia (pain during sexual relations) directly related to fibroid.

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

Refer to Corporate Medical Policy #7.01.03 Cryosurgical Tumor Ablation

Refer to Corporate Medical Policy #7.02.07 Liver Transplantation

Refer to Corporate Medical Policy #7.01.69 Selective Internal Radiation Therapy (SIRT) for Hepatic Tumors

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services

DESCRIPTION

Radiofrequency is an ablative technique that relies on heat to effect tumor killing. A radiofrequency electrode is passed into a tumor under sonographic, computerized tomography (CT) or magnetic resonance (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 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, bone and uterine fibroids.

RFA can be administered by open surgery, laparoscopic surgery or percutaneously.

Uterine fibroids, (UF) also referred to as leiomyomas or myomas, are benign noncancerous tumors of the myometrium, the smooth muscle layer of the uterus. UF remain a major women's health issue with significant economic and reproductive impact. UF represent the most common gynecological tumor in women of reproductive age and are responsible for over 200,000 hysterectomies per year. Most fibroids, even large ones, do not produce symptoms. However, they can cause a variety of symptoms including menometrorrhagia, dysmenorrhea, pelvic pain, reproductive failure, and compression of adjacent pelvic viscera, or be totally asymptomatic. They occur in almost 70% of Caucasian women and in greater than 80% of African American women by age 50. A standardized leiomyoma subclassification system was developed by the International Federation of Gynecology and Obstetrics (FIGO) to describe uterine leiomyoma location in relation to the endometrial and serosal surfaces.

RFA was Food and Drug Administration (FDA) approved as a treatment for symptomatic myomas in 2012 and has been shown to reduce heavy menstrual bleeding, pelvic pain, and other associated symptoms. The radiofrequency ablation system Acessa for UF, received FDA clearance for marketing on November 5, 2012 (K121858). The device is indicated for use in percutaneous, laparoscopic coagulation and ablation of soft tissue, including treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance. The next generation of the Acessa System, The Acessa ProVu System, received FDA clearance on September 28, 2018. It is indicated for use in percutaneous, laparoscopic coagulation and ablation of soft tissue, including treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance. In the Acessa procedure, a controlled volume of heat is applied directly to the fibroid, killing the tissue of the fibroid while leaving healthy surrounding tissue unharmed. The dead tissue is reabsorbed by the body. The Sonata Sonography-Guided Transcervical Fibroid Ablation System(Gynesonics) received FDA clearance for marketing on August 15, 2018. This device is intended for diagnostic intrauterine imaging and transcervical treatment of symptomatic uterine fibroids, including those associated with heavy menstrual bleeding.

RATIONALE

RFA of liver tumors is not ubject 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 of RFA of renal tumors were small case series of individual institution experiences with this treatment modality. Patients in these case series had small renal tumors that 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 whether RFA provides a durable survival benefit. RFA as an alternative to surgical intervention requires comparative studies, to determine whether it provides a similar survival benefit.

The National Comprehensive Cancer Network (NCCN) Practice Guideline on kidney cancer (V3.2024) states that thermal ablation (e.g., cryosurgery, radiofrequency ablation, microwave ablation) is an option for the management of patients with clinical Stage T1 renal lesions. Thermal ablation is an option for massess less than three cm, but may also be an option for larger masses in select patients. Ablation in masses greater than three cm is associated with higher rates of local recurrence/persistence and complications.

Lung Tumors

While the available studies of RFA of lung tumors 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 that 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 the 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…"

Transplant Setting

The drop out rates of patients with hepatocellular carcinoma (HCC) from liver transplant lists have been reported to range from 20-40% due to tumor progression. Recent studies utilizing RFA 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 specifically to 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 RFA for osteoid osteomas provide evidence that RFA achieves outcomes comparable to surgical excision, in terms of 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 the location of which makes 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 with respect to 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 on the use of RFA on patients with bone metastases consists of uncontrolled studies with only a limited number of cases. However, the patient populations enrolled in the studies comprised individuals with limited or no treatment options, for whom short-term pain relief was 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.

The National Comprehensive Cancer Network (NCCN) Practice Guideline on thyroid cancer (V2.2024) states that for patients with papillary thyroid carcinoma and locoregional recurrence, local therapies (ethanol ablation, RFA) when available may be considered in select patients with limited burden nodal disease.

Neuroendocrine and Adrenal Tumors

The National Comprehensive Cancer Network (NCCN) Practice Guideline on neuroendocrine and adrenal tumors (V1.2023) states that cytoreductive surgery or ablation therapy such as RFA or cryoablation may be considered if near-complete treatment of tumor burden can be achieved (category 2B). Ablative therapy in this setting is non-curative. Data on the use of these interventions are emerging.

Uterine Fibroids

The American College of Gynecology (ACOG) released an updated practice bulletin in mid-2021 stating that laparscopic RFA can be considered as a minimally invasive treatment option for the management of symptomatic leiomyomas in patients who desire uterine preservation and are counseled about the limited available data on reproductive outcomes.

The American Association of Gynecologic Laparoscopists (AAGL) (2022) commented that current review of the literature suggests that RFA offers a safe and effective alternative treatment option for patients with symptomatic fibroids who seek uterine preservation. Although RFA is not yet approved by the FDA as a fertility-enabling treatment, subsequent successful pregnancy outcomes have been reported in the literature. More robust fertility data is required to confirm its safety for those who actively desire future pregnancy. RFA is another promising, conservative fibroid treatment and is looking to be an essential component of the minimally invasive gynecologist's armamentarium.

CODES

- *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 Codes

Code	Description
20982	Ablation therapy for reduction or eradiation of one 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, including imaging guidance when performed, radiofrequency, unilateral

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, one or more liver tumor(s), percutaneous, radiofrequency
50592	Ablation, one or more renal tumor(s), percutaneous, unilateral, radiofrequency
58674	Laparoscopy, surgical, ablation of uterine fibroid(s), including intraoperative ultrasound guidance and monitoring, radiofrequency
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
58580 Effective 01/01/24	Transcervical ablation of uterine fibroid(s), including intraoperative ultrasound guidance and monitoring, radiofrequency (Effective 01/01/24) (Replacing 0404T)
0404T Termed 12/31/23	Transcervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency

HCPCS Codes

Code	Description
No specific code(s)	

ICD10 Codes

Code	Description
C22.0-C22.9	Malignancies of liver and intrahepatic bile ducts (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-D16.9	Benign neoplasm of short bones of upper and lower limbs (code range)
218.0-218.9	Uterine leiomyoma (code range)
D25.0-D25.9	Leiomyoma of uterus (code range)
Investigational diagnosis codes:	
174.0-174.9	Malignant neoplasm of female breast (code range)
610.2	Fibroadenosis of breast

Code	Description
C50.011-C50.919	Malignant neoplasm of breast (code range)
N60.21-N60.29	Fibroadenosis of breast (code range)

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*Key Article

KEY WORDS

Radiofrequency ablation

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based on our review, Radiofrequency Tumor Ablation is not addressed in National or Regional Medicare coverage determinations or policies.