Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors

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Section: Medicine

Place(s) of Service: Outpatient

I. Description

In radiofrequency ablation (RFA), a probe is inserted into the center of a tumor and the non-insulated electrodes, which are shaped like prongs, are projected into the tumor; a heat is then 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 cm to 5.5 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. Radiofrequency ablation may be performed percutaneously, laparoscopically, or as an open procedure.

Palliation for Bone Metastases

The evidence for RFA in patients who have painful osteolytic bone metastases includes a number of case series of RFA for palliation of pain. Relevant outcomes are overall survival, disease-specific survival, symptoms, change in disease status, morbid events, functional outcomes, quality of life, and treatment-related morbidity. The patient population is comprised of patients with limited or no treatment options, for whom short-term pain relief is an appropriate clinical outcome. Therefore, the evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

Osteoid Osteomas

The evidence for RFA in patients who have osteoid osteoma includes case series. Relevant outcomes are symptoms, change in disease status, morbid events, functional outcomes, quality of life, and treatment-related morbidity. Although no randomized trials of RFA for osteoid osteomas have been performed, the uncontrolled studies have demonstrated RFA can provide adequate symptomatic relief with minimal complications in patients with limited or no other treatment options, for whom short-term symptom relief and avoidance of invasive procedures are appropriate clinical outcomes. Therefore, the evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.
Renal Cell Carcinoma

The evidence for RFA in patients who have small renal carcinomas includes a large number of observational studies and systematic reviews of these studies. Relevant outcomes are overall survival, disease-specific survival, symptoms, change in disease status, morbid events, functional outcomes, quality of life, and treatment-related morbidity. The evidence shows that the use of RFA results in adequate survival and tumor control with low complication rates in patients who are not surgical candidates due to comorbid conditions or who have baseline renal insufficiency such that standard surgical procedures would impair their kidney function. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

Non-Small-Cell Lung Cancer

The evidence for RFA in patients who have peripheral, stage 1 non-small-cell lung carcinomas includes a large number of observational studies and systematic reviews of these studies. Relevant outcomes are overall survival, disease-specific survival, symptoms, change in disease status, morbid events, functional outcomes, quality of life, and treatment-related morbidity. In general, the evidence shows RFA results in adequate survival and tumor control with low complication rates in patients who are not surgical candidates due to comorbid conditions that impair their cardiopulmonary function. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

Pulmonary Metastases

The evidence for RFA in patients who have metastatic pulmonary tumors includes numerous observational studies and systematic reviews of these studies. Relevant outcomes are overall survival, disease-specific survival, symptoms, change in disease status, morbid events, functional outcomes, quality of life, and treatment-related morbidity. In general, the evidence shows RFA results in adequate survival and tumor control with low complication rates in patients who are not surgical candidates due to comorbid conditions that impair their cardiopulmonary function. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

Miscellaneous Tumors

Breast Tumors

The evidence for RFA in patients who have breast tumors includes observational studies and systematic reviews of these studies. Relevant outcomes are overall survival, disease-specific survival, symptoms, change in disease status, morbid events, functional outcomes, quality of life, and treatment-related morbidity. Evidence has reported varied and incomplete ablation rates with concerns about postablation tumor cell viability. Long-term improvements in health outcomes have not been demonstrated. Additionally, available studies do not allow comparisons with conventional breast-conserving procedures. Further studies, with long-term follow-up, are needed to determine whether RFA for small breast cancers can provide local control and survival rates comparable with
conventional breast-conserving treatment. The evidence is insufficient to determine the effects of the technology on health outcomes.

Head and Neck Tumors

The evidence for RFA in patients who have head and neck tumors includes small case series. Relevant outcomes are overall survival, disease-specific survival, symptoms, change in disease status, morbid events, functional outcomes, quality of life, and treatment-related morbidity. While RFA may have a role in palliation, complications are common and severe. The evidence is insufficient to determine the effects of the technology on health outcomes.

Thyroid Tumors

The evidence for RFA in patients who have thyroid tumors includes case series and uncontrolled studies. Relevant outcomes are overall survival, disease-specific survival, symptoms, change in disease status, morbid events, functional outcomes, quality of life, and treatment-related morbidity. While RFA has been shown to reduce thyroid tumor volume and improve clinical symptoms, complications can be common. The evidence is insufficient to determine the impact of the technology on health outcomes.

Other Miscellaneous Tumors

The evidence for RFA in patients who have a variety of miscellaneous tumors including adrenal, soft tissue neoplasms, solid malignancies, pancreas, hamartoma, rectosigmoid, rectal and colorectal tumors, includes small case series and observational studies. Relevant outcomes are overall survival, disease-specific survival, symptoms, change in disease status, morbid events, functional outcomes, quality of life, and treatment-related morbidity. The evidence is insufficient to determine the impact of the technology on health outcomes.

II. Criteria/Guidelines

A. Radiofrequency ablation is covered (subject to Limitations and Administrative Guidelines) in the following situations:

1. To palliate pain in patients with osteolytic bone metastases who have failed or are poor candidates for standard treatments such as radiation or opioids
2. To treat osteoid osteomas that cannot be managed successfully with medical treatment
3. To treat localized renal cell carcinoma that is no more than 4 cm in size when either of the following criteria are met:
   a. In order to preserve kidney function in patients with significantly impaired renal function (i.e., the patient has one kidney or renal insufficiency defined by a glomerular filtration rate [GFR] of less than 60 mL/min per m²) when the standard surgical approach (i.e., resection of renal tissue) is likely to substantially worsen existing kidney function
   b. The patient is not considered a surgical candidate

B. Radiofrequency ablation is covered (subject to Limitations and Administrative Guidelines) to treat an isolated peripheral non-small cell lung cancer lesion that is no more than 3 cm in size when all of the following criteria are met:
1. 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

2. Tumor is located at least 1 cm from the trachea, main bronchi, esophagus, aorta, aortic arch branches, pulmonary artery and the heart

C. Radiofrequency ablation is covered (subject to Limitations and Administrative Guidelines) to treat malignant non-pulmonary tumor(s) metastatic to the lung that are no more than 3 cm in size when all of the following criteria are met:

1. Tumors should be amenable to complete ablation
2. In order to preserve lung function when surgical resection or radiation treatment is likely to substantially worsen pulmonary status OR the patient is not considered a surgical candidate
3. There is no evidence of extrapulmonary metastases; AND the tumor is located at least 1 cm from the trachea, main bronchi, esophagus, aorta, aortic arch branches, pulmonary artery and the heart

III. Limitations

A. Radiofrequency ablation is not covered to treat the following:
   1. Breast tumors
   2. Lung cancer not meeting the criteria above
   3. Renal cell cancer not meeting the criteria above
   4. All other tumors outside the liver including, but not limited to, the head and neck, thyroid, adrenal gland, ovary, and pelvic/abdominal metastases of unspecified origin
   5. Osteoid osteomas that can be managed with medical treatment
   6. Painful bony metastases as initial treatment

B. Radiofrequency ablation for malignant non-pulmonary tumor(s) metastatic to the lung is limited to three tumors per lung

C. Twelve months should elapse before a repeat ablation is considered, for malignant non-pulmonary tumor(s) metastatic to the lung

IV. Administrative Guidelines

A. Precertification is required. Complete HMSA's precertification request and fax or mail the form as indicated. Include the following documentation:
   1. Current history and physical documenting the patient's condition including any comorbidities
   2. Imaging studies

B. Applicable Codes:

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<tr>
<th>CPT Code</th>
<th>Description</th>
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<tr>
<td>20982</td>
<td>Ablation, bone tumor(s) (e.g., osteoid osteoma, metastasis) radiofrequency, percutaneous, including computed tomographic guidance</td>
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V. Background

RFA is being evaluated to treat various tumors, including inoperable tumors, or to treat patients ineligible for surgery due to age, presence of comorbidities, or poor general health. Goals of RFA may include 1) controlling local tumor growth and preventing recurrence; 2) palliating symptoms; and 3) extending survival duration for patients with certain tumors. The effective volume of RFA depends on the frequency and duration of applied current, local tissue characteristics, and probe configuration (e.g., single vs. multiple tips). RFA can be performed as an open surgical procedure, laparoscopically or percutaneously, with ultrasound or computed tomography (CT) guidance.

Potential complications associated with RFA include those caused by heat damage to normal tissue adjacent to the tumor (e.g., intestinal damage during RFA of kidney), structural damage along the probe track (e.g., pneumothorax as a consequence of procedures on the lung), or secondary tumors if cells seed during probe removal.

Recently, reports have been published on use of RFA to treat renal cell carcinomas, breast tumors, pulmonary cancers (including primary and metastatic lung tumors), bone, and other tumors. For some of these, RFA is being investigated as an alternative to surgery for operable tumors. Well-established local or systemic treatment alternatives are available for each of these malignancies. The hypothesized advantages of RFA for these cancers include improved local control and those common to any minimally invasive procedure (e.g., preserving normal organ tissue, decreasing morbidity, decreasing length of hospitalization).

Palliation for bone metastases.

After lung and liver, bone is the third most common metastatic site and is relatively frequent among patients with primary malignancies of the breast, prostate, and lung. Bone metastases often cause osteolysis (bone breakdown), resulting in pain, fractures, decreased mobility, and reduced quality of life. External-beam irradiation often is the initial palliative therapy for osteolytic bone metastases. However, pain from bone metastases is refractory to radiation therapy in 20–30% of patients, while recurrent pain at previously irradiated sites may be ineligible for additional radiation due to risks of normal tissue damage. Other alternatives include hormonal therapy, radiopharmaceuticals such as strontium 89, and bisphosphonates. Less often, surgery or chemotherapy may be used for palliation, and intractable pain may require opioid medications. RFA has been investigated as another alternative for palliating pain from bone metastases.

Osteoid osteomas
Osteomas are the most common benign bone tumor, comprising 10–20% of benign and 2–3% of all bone tumors. They are typically seen in children and young adults, with most diagnosed in patients between 5–20 years of age. Osteomas are most common in the lower extremity (usually the long bones, mainly the femur) and less common in the spine. These tumors typically have a characteristic clinical presentation and radiologic appearance, with pain, usually continuous and worse at night, and usually relieved by aspirin or other nonsteroidal anti-inflammatory drugs (NSAIDs). The natural history of the osteoid osteoma varies based upon its location, and although they rarely exceed 1.5 cm, may produce bone widening and deformation, limb length inequality, or angular deviations when near a growth plate. When located in the spine, these lesions may lead to painful scoliosis or torticollis. Sometimes, they heal spontaneously after 3–7 years.

Treatment options include medical management with nonsteroidal anti-inflammatory drugs (NSAIDs), surgical excision (wide/en bloc excision or curetting), or the use of CT- or magnetic resonance imaging (MRI)-guided minimally invasive procedures including core drill excision, laser photocoagulation, or RFA. For many years, complete surgical excision was the classic treatment of osteomas, usually performed in patients with pain despite medical management. Complete surgical excision has several disadvantages. A substantial incision may be necessary and removal of a considerable amount of bone (especially in the neck of the femur), increases the need for bone grafting and/or internal fixation (which often necessitates a second procedure to remove the metal work). Other possible risks include avascular necrosis of the femoral head and postoperative pathologic fracture. In addition, surgical excision leads to a lengthier period of convalescence and postoperative immobilization. Anatomically inaccessible tumors may not be completely resectable and may recur. RFA of osteoid osteoma is done with a needle puncture, so no incision or sutures are needed, and patients may immediately walk on the treated extremity and return to daily activities as soon as the anesthetic effect wears off. The risk of recurrence with RFA of an osteoma is 5–10%, and recurrent tumors can be retreated with RFA. In general, RFA is not performed in many spinal osteomas because of possible thermal-related nerve damage.

Renal cell carcinoma

Radical nephrectomy remains the principal treatment of RCC, however, partial nephrectomy or nephron-sparing surgery has been shown to be as effective as radical nephrectomy, with comparable long-term recurrence-free survival rates, in a select group of patients. Alternative therapy such as RFA is of interest in patients with small renal tumors when preservation of renal function is necessary (e.g., in patients with marginal renal function, a solitary kidney, bilateral tumors) and in patients with comorbidities that would render them unfit for surgery. Another consideration would be in patients at high risk of developing additional renal cancers (as in von Hippel-Lindau disease).

Primary Pulmonary Tumors and Metastases

Surgery is the current treatment of choice in patients with stage 1 primary non-small cell lung carcinoma (NSCLC). (Stage 1 includes 1a: T1N0M0 and 1b: T2N0M0). Only approximately 20% of patients present with stage 1 disease, although this number is expected to increase as a result of screening programs, advances in imaging modalities, and widespread use of CT scans for other
indications. Postsurgical recurrence rates of stage 1 NSCLC have been reported between 20% and 30%, with most occurring at distant sites; locoregional recurrences occur in approximately 12%. Large differences in survival outcome are observed after surgery in stage 1 patients, with 5-year overall survival (OS) rates, ranging from 77% for small T1 tumors to 35% for large T2 tumors. Untreated, stage 1 NSCLC has a 5-year OS rate of 6–14%.

Patients with early stage NSCLC who are not surgical candidates may be candidates for radiation treatment with curative intent. In the two largest retrospective radiation therapy series, patients with inoperable disease treated with definitive radiation therapy achieved 5-year survival rates of 10% and 27%. In both studies, patients with T1N0 tumors had better 5-year survival rates of 60% and 32%, respectively.

RFA is being investigated in patients who are medically inoperable, with small primary lung cancers or lung metastases.

Miscellaneous Tumors

Radiofrequency ablation has been investigated for use in individuals with a number of different lesions in different anatomic sites. This includes, but is not limited to, breast, head and neck, and thyroid tumors

Breast tumors

There has been a trend in the treatment of small breast cancers from total mastectomy toward increasingly more conservative treatment options such as lumpectomy, with more acceptable cosmetic outcomes and preservation of the breast. The selection of surgical approach balances the patient’s desire for breast conservation and the need for tumor-free margins in resected tissue. Minimally invasive nonsurgical techniques such as RFA are appealing if they can produce local control and survival equivalent to breast-conserving surgical alternatives. Nonsurgical ablative techniques pose difficulties such as the inability to determine tumor size, complete tumor cell killing, and local recurrence. Additionally, RFA can cause burning of the skin or damage to muscle, possibly limiting use in patients with tumors near the skin or chest wall.

Head and neck cancer

In patients with head and neck cancer with recurrent disease, surgical salvage attempts are poor in terms of local control, survival, and quality of life and these recurrent tumors are often untreatable with standard salvage therapies. Palliative chemotherapy or comfort measures may be offered. The safety and efficacy of RFA has been investigated as an option for palliative treatment in these situations.

Thyroid tumors

Surgical resection is the primary treatment choice for medically unresponsive, symptomatic benign thyroid tumors and thyroid carcinomas. However, techniques for ablation of thyroid tumors (e.g., RFA and microwave ablation) are being investigated.
VI. Rationale

Palliation of Pain from Bone Metastases

Goetz et al. reported on an international study (n=43) conducted at 9 centers in which patients with painful osteolytic bone metastases were treated palliatively with radiofrequency ablation (RFA). The study’s primary outcome measure was the Brief Pain Inventory-Short Form, a validated scale from 0 for no pain to 10 for worst pain imaginable. Patient eligibility required baseline values of 4 or more from 2 or fewer painful sites. Thirty-nine (91%) of the patients had previously received opioids to control pain from the lesion(s) treated with RFA, and 32 (74%) had prior radiation therapy to the same lesion. Mean pain score at baseline was 7.9 (range: 4–10). At 4, 12, and 24 weeks after RFA, average pain scores decreased to 4.5, 3.0, and 1.4, respectively (all p<0.0005). Forty-one (95%) of the patients achieved a clinically significant improvement in pain scores, prospectively defined as a decrease of 2 units from baseline. Investigators also reported statistically significant (p=0.01) decreases in opioid use at weeks 8 (by 59%) and 12 (by 54%).

An earlier case series showed that palliative RFA provided significant pain relief in 9 of 10 (90%) patients with unresectable, osteolytic spine metastases who had no other treatment options. Pain was reduced by an average of 74%; back-pain-related disability was reduced by an average of 27%. Neurologic function was preserved in 9 patients and improved in 1. An additional small case series of 24 patients with painful metastatic bone tumors who experienced pain-alleviating effects with RFA supports the policy statement.

Osteoid Tumors

Systematic Reviews

Lanza et al reported on a systematic review of percutaneous thermal ablation for osteoid osteomas in 2014. Included in the review were 23 articles on RFA, 3 on interstitial laser ablation and 1 with a combination of ablation techniques, totaling 27 articles and 1772 patients. Mean technical success was 100% and clinical success, defined as being pain-free, ranged from 94% to 98%, depending on length of follow-up. Complications occurred in 2% of patients and included skin or muscle burn in 9 patients, 4 infections, nerve lesions or tool breakage in 3 patients each, delayed skin healing, hematoma, and failure to reach target temperature in 2 patients each and fracture, pulmonary aspiration, thrombophlebitis, and cardiac arrest in 1 patient each. Eighty-six patients had tumor recurrence.

Clinical Studies

An observational study published in 2015 evaluated long-term clinical outcomes after computed tomography (CT)–guided RFA in patients diagnosed with osteoid osteoma located in the upper and lower extremities. The study population included 52 patients with a typical clinical history and radiologically confirmed osteoid osteoma who received CT-guided RFA treatment from 1998 to February 2014 at Aarhus University Hospital, Denmark. The clinical outcome was evaluated based on patient-reported outcome measures and medical record review. The response rate was 52 of 60 (87%). After 1 RFA treatment, 46 of 52 (88%) of the patients experienced pain relief, and 51 of 52 (98%) of the patients had pain relief after repeat RFA. One patient underwent open resection after
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RFA. No major complications were reported; 4 patients reported minor complications including small skin burn, minor skin infection and hypoesthesia at the entry point. In all, 50 of 52 (96%) patients were reported to be "very satisfied" with the RFA treatment.

In 2012, Rimondi et al reported on a retrospective study of 557 patients treated with CT-guided RFA as primary treatment for nonspinal osteoid osteomas. All patients were followed for a mean of 3.5 years (0.5–9 years). Pain relief occurred in all 557 patients within the first week after RFA and continued in 533 patients (96%) who remained asymptomatic through their last follow-up. Pain recurrence occurred in 24 patients (4%). Complications occurred in 5 patients and included thrombophlebitis, a skin burn, a broken electrode, and 2 procedures in which the RFA generator failed to reach maximum temperature.

In 2011, Rimondi and colleagues reported on a retrospective study of 557 patients treated with CT-guided RFA as primary treatment for non-spinal osteoid osteomas. All patients were followed for a mean of 3.5 years (0.5–9 years). Pain relief occurred in all 557 patients within the first week after RFA and continued in 533 patients (96%) who remained asymptomatic through their last follow-up. Pain recurrence occurred in 24 patients (4%). Complications occurred in 5 patients and included thrombophlebitis, a skin burn, a broken electrode and 2 procedures in which the RFA generator didn’t reach maximum temperature.

In 2003, Rosenthal and colleagues reported their experience over a 11-year period with 271 RFA procedures for osteoid osteomas in 263 patients. Short-term outcome was evaluated to detect procedure-related problems; by this definition, all procedures were considered technically successful. Long-term clinical success data (defined as being free of pain without the necessity of additional procedures) were available in 126 patients, with a complete clinical success observed in 89%. For procedures performed as the initial treatment, the success rate was 91%.

In 2004, Cioni and colleagues reported on a case series of 38 patients with osteoid osteoma diagnosed clinically, as well as by radiography, scintigraphy, contrast-enhanced magnetic resonance imaging (MRI), and computed tomography (CT). A total of 30 of the 38 patients reported prompt pain relief. Six of the remaining 8 patients underwent successful retreatment, and 2 underwent surgical excision.

Another recent case series reported primary success in 37 of 38 (97%) patients (age range: 5–43 years) who underwent CT-guided percutaneous RFA to treat clinically and radiologically suspected osteoid osteoma. Lesions were located in the proximal femur (n=13), tibia (n=5), foot (n=5), spine and fibula (n=3 each), acetabulum and humerus (n=2 each), and 5 in other sites. All patients experienced sufficient pain relief to permit resumption of normal activities within 24 hours of the procedure. During follow-up, ranging from 3–24 months, no major complications were reported.

Renal Tumors
Systematic Reviews

In 2014, Wang et al reported on a systematic review and meta-analysis of studies on RFA and partial nephrectomy for stage 1 renal tumors. Included in the review were 166 studies with a total of 9565 patients. The rate of local progression was greater with RFA than laparoscopic/robotic or
open partial nephrectomy (4.6%, 1.2%, 1.9%, respectively; p<0.001). RFA had more frequent minor complications than laparoscopic/robotic or open partial nephrectomy (13.8%, 7.5%, 9.5%, respectively; p<0.001). However, the rate of major complications was greater with open partial nephrectomy than laparoscopic/robotic partial nephrectomy or RFA (7.9%, 7.9%, 3.1%, respectively, p<0.001).

In another 2014 systematic review and meta-analysis, Katsanos et al reviewed 1 RCT and 5 cohort studies (N=587) on thermal ablation (RFA or microwave) or nephrectomy for small renal tumors with a mean size of 2.5 cm. The local recurrence rate was 3.6% in both groups (risk ratio [RR], 0.92; 95% confidence interval [CI], 0.4 to 2.14; p=0.79). Disease-free survival was also similar in both groups up to 5 years (hazard ratio, 1.04; 95% CI, 0.48 to 2.24; p=0.92). However, the overall rate of complications was significantly lower in the patients undergoing ablation versus nephrectomy (7.4 vs 11.1%, respectively; pooled RR=0.55; 95% CI, 0.31 to 0.97; p=0.04).

In 2012, El Dib and colleagues conducted a meta-analysis evaluating RFA and cryoablation for small renal masses. Included in the review were 11 RFA case series (totaling 426 patients) and 20 cryoablation case series (totaling 457 patients) published through January 2011. Mean tumor size was 2.7 cm (range from 2 to 4.3 cm) in the RFA group and 2.5 cm (range from 2 to 4.2 cm) in the cryoablation group. Mean follow-up times for the RFA and cryoablation groups were 18.1 and 17.9 months, respectively. Clinical efficacy, defined as cancer-specific survival rate, radiographic success, no evidence of local tumor progression, or distant metastases, was not significantly different between groups. The pooled proportion of clinical efficacy for RFA was 90% (95% CI: 0.86–0.93) and 89% (95% confidence interval [CI]: 0.83–0.94) for cryoablation.

Kunkle and Uzzo conducted a comparative meta-analysis evaluating cryoablation and RFA as primary treatment for small renal masses. Forty-seven case series representing 1,375 renal tumors were analyzed. Of 600 lesions treated with cryoablation, 494 underwent biopsy before treatment versus 482 of 775 treated with RFA. The incidence of renal carcinoma (RCC) with known pathology was 71.7% in the cryoablation group and 90% in the RFA group. The mean duration of follow-up after RFA was 15.8 months. Local tumor progression was reported in 31 of 600 lesions after cryoablation and in 100 of 775 lesions after RFA, a difference that was significant (p<0.0001). Progression to metastatic disease was described in 6 of 600 lesions after cryoablation versus 19 of 775 after RFA (p=0.06). The authors caution that minimally invasive ablation generally has been performed selectively on older patients with smaller tumors, possibly resulting in selection bias; series of ablated lesions tend to have shorter post-treatment follow-up compared with tumors managed by surgical excision or active surveillance, and treatment efficacy may be overestimated in series that include tumors with unknown pathology.

In 2010, Salas and colleagues reviewed 17 studies identified from literature published between 2003 and 2009. The authors found RFA has proven to demonstrate oncologic outcomes that are almost equivalent to surgical resection when treating renal tumors with a mean size less than 4.0 cm. Renal function also declines minimally and is significantly lower than surgical resection. Van Poppel et al. also conducted a review of the literature published between 2004 and May 2011. In this review, the authors concluded RFA is a reasonable treatment option for most low-grade renal tumors less than 4 cm in patients who are not candidates for surgical resection or active
surveillance. The authors noted the need for long-term prospective studies to compare ablative techniques for renal ablation, such as RFA versus cryoablation.

A 2008 review article summarized the literature, which included 713 patients who underwent RFA of 866 renal tumors with an average follow-up of 12.6 months. The average tumor-free survival rate was 85.4%. The author notes that across different study reports, there are significant variations in the practice of RFA for kidney tumors, including the types of devices used, imaging modality and performance experience, making it difficult to compare results across studies.

Clinical Studies

Stern and colleagues retrospectively compared patients with stage T1a renal tumors, confirmed by pathology to be renal cell carcinoma (RCC), treated with either partial nephrectomy (n=34) or RFA (n=34). The mean follow-up for the partial nephrectomy group was 47 months (range: 24–93) and for the RFA group, 30 months (range: 18–42). Three-year recurrence-free survival rate was 95.2% for partial nephrectomy and 91.4% for RFA (p=0.58). There were no disease-specific deaths in either group. In this small study, intermediate outcomes for patients with T1a renal cell carcinomas were similar whether treated with partial nephrectomy or RFA.

Primary Pulmonary Tumors and Metastases

In 2013, the Agency for Healthcare Research and Quality (AHRQ) published a Comparative Effectiveness Review of local nonsurgical therapies for stage I non-small-cell lung cancer (NSCLC). In this review, no comparative RFA studies were identified. The AHRQ report found available evidence is insufficient to draw conclusions on the comparative effectiveness of local nonsurgical therapies for NSCLC, including RFA.

In a 2013 systematic review of RFA, surgery, and SBRT for colorectal cancer lung metastases, no randomized trials were identified, and evidence was also insufficient to draw conclusions on the comparative effectiveness of these therapies.

In a 2011 evidence-based review, 46 studies on RFA for lung tumors were evaluated, which included 2,905 ablations in 1,584 patients with a mean tumor size of 2.8 ± 1.0 cm. Twenty-four studies (51.2%) reported rates of local recurrence, which ranged from 0% to 64% and occurred in 282 cases (12.2%) within a mean follow-up time of 13 months (range 3–45 months of 19 studies reporting). Primary lung cancer rates of local recurrence were not significantly different at 22.2% than for metastases at 18.1%. Twenty-one studies reported rates of overall survival, which ranged from 25% to 100% with a mean of 59.4% and a mean follow-up time of 17.7 ± 12.4 months. The mean cancer-specific survival rate was 82.6%, as reported in 24 studies with a range of 55% to 100% with a mean of 17.4 ± 14.1 months follow-up. Mean overall morbidity was 24.6% and most commonly included pneumothorax (28.3%), pleural effusion (14.8%), and pain (14.1%). Mortality related to the RFA procedure was 0.21% overall.

A 2008 systematic review of RFA for primary and secondary lung tumors included studies that reported procedure-related morbidity and mortality, rates of complete tumor ablation, local recurrence and/or OS. Seventeen studies were included for a total of 707 patients (range: 12–142), and all were observational case series with no control groups and were classified as poor quality by
the authors of the systematic review. No RCTs or comparative studies were found. The definition of nonsurgical candidates differed from study to study, and there were differences in the criteria used for tumor resectability. An additional confounding factor was that in some studies, additional therapies were used with RFA, such as systemic chemotherapy. The mean size of lesions treated ranged from 1.7 cm to 5.2 cm (median: 2.2 cm). Seven of the studies reported survival; 3 reported on 3-year survival rates. One-, 2-, and 3-year survival rates ranged from 63–85%, 55–65%, and 15–45%, respectively. The authors of the systematic review concluded that there is limited evidence reporting clinical outcomes of RFA treatment of lung tumors and that the quality of the evidence is relatively low, with no RCTs or case-control trials comparing the use of RFA with conventional treatment for nonsurgical patients. Of the studies that they included in their review, there were a wide range in results of local recurrence rates, heterogeneity of the patients selected, and tumor characteristics, and relatively short follow-up in most.

In a 2012 review of evidence from 16 studies, Bilal and colleagues compared RFA to stereotactic ablative radiotherapy (SABR) in patients with inoperable early stage non-small cell lung cancer (NSCLC). The authors found overall survival rates for RFA and SABR were similar in patients at 1 year (68.2–95% vs. 81–85.7%) and 3 years (36–87.5% vs. 42.7–56%, all respectively). However, survival rates at 5 years were lower with RFA (20.1–27%) than with SABR (47%). Caution must be used in interpreting these findings drawn from comparisons of results from uncontrolled, case series and retrospective reviews.

Clinical studies

In 2010, Zemlyak and colleagues prospectively compared 3 treatments for medically inoperable patients with stage I non-small cell lung cancer (NSCLC): RFA in 12 patients, sublobar resection in 25 patients and percutaneous cryoablation in 27 patients. At 3 years follow-up, survival rates were not significantly different between groups. Overall and cancer-specific 3-year survivals were 87.5%, 87.1% and 77% and 87.5%, 90.6% and 90.2%, respectively. The authors concluded any of the 3 procedures were reasonable options for treatment of lung tumors in patients unfit for major surgery. The authors noted since surgeons chose the treatment option with patient input for this study, selection bias limits interpretation of his study, and further studies are warranted. In 2011, Huang and colleagues prospectively followed 329 consecutive patients treated with RFA for lung tumors (237 primary and 92 metastatic). Complications were experienced by 34.3% (113) of patients and were most commonly pneumothorax (19.1%). Overall survival at 2 and 5 years was 35.3% and 20.1%, respectively. The risk of local progression was not significantly different in tumors less than 4 cm but became significant in tumors greater than 4 cm.

A prospective, single-arm, multicenter trial from 7 centers in Europe, the U.S., and Australia reported the technical success, safety, response of tumors, and survival in 106 patients with 183 lung tumors. All patients were considered to be unsuitable for surgery and unfit for radiotherapy or chemotherapy. Tumors measured less than 3.5 cm (mean 1.7 cm; standard deviation [SD] 1.3) and included patients with NSCLC (n=22), colorectal metastases (n=41), and other metastases (n=16). Technical success rate was 99%. Patients were followed for 2 years, and a confirmed complete response lasting at least 1 year was observed in 88% of assessable patients, with no differences in response rate between patients with primary and metastatic tumors. Overall survival in patients
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with NSCLC was 70% at 1 year (95% confidence interval [CI]: 51–83%; cancer-specific survival 92% [78–98%], and 48% at 2 years (95% CI: 30–65%; cancer-specific survival 73% [54–86%]). Overall survival in patients with metastatic colorectal cancer was 89% at 1 year (95% CI: 76–95%; cancer-specific survival 91% [78–96%]) and 66% at 2 years (95% CI: 53–79%; cancer-specific survival 68% [54–80%]). Overall survival in patients with other metastases was 92% at 1 year (95% CI: 65–99%; cancer-specific survival 93% [67–99%]) and 64% at 2 years (43–82%; cancer-specific survival 67% [48–84%]). Patients with stage 1 NSCLC (n=13) had OS rates of 75% (45–92%) at 2 years (cancer-specific 92% [66–99%]). No differences in response were seen between patients with NSCLC or lung metastases.

Zhu and colleagues reported on a study to assess the incidence and risk factors of various complications after RFA of pulmonary neoplasms. The authors prospectively evaluated the clinical and treatment-related data regarding 129 consecutive percutaneous radiofrequency ablation treatment sessions for 100 patients with inoperable lung tumors. In this study, there was no post-procedural mortality. The overall morbidity rate was 43% (n=55 of 129). The most common adverse effect was pneumothorax, occurring in 32% (n=41 of 129) of treatment sessions. Other significant complications included pleuritic chest pain (18%), hemoptysis (7%), pleural effusions (12%), and chest drain insertion (20%). Both univariate and multivariate analyses identified more than 2 lesions ablated per session as a significant risk factor for overall morbidity, pneumothorax, and chest drain insertion. Length of the ablation probe trajectory greater than 3 cm was an additional independent risk factor for overall morbidity and pneumothorax.

In 2009, Pennathur et al. reported on 100 patients with inoperable lung tumors. Forty-six patients had primary lung neoplasm, 25 had recurrent cancer, and 29 had pulmonary metastases. Mean follow-up was 17 months. Median OS for all patients was 23 months. The probability of 2-year OS for primary lung cancer patients, recurrent cancer patients, and metastatic cancer patients was 50% (95% CI: 33–65%), 55% (95% CI: 25–77%), and 41% (95% CI: 19–62%), respectively. In a retrospective review, Beland et al. reviewed recurrence patterns in patients with primary NSCLC treated with RFA between 1998 and 2008. Ninety-one patients were identified and 10 excluded because of lack of post-treatment imaging results or multiple treated lung cancers (n=2). Mean tumor size was 2.5 cm (range: 1-5.5 cm). Nineteen patients had adjuvant external beam radiation, and 9 had brachytherapy. At follow-up imaging at a mean of 17 months (range: 1–72 months), 45 patients demonstrated no evidence of recurrence. Recurrence after RFA was local in 13 cases, intrapulmonary in 6, nodal in 6, mixed in 2, and distant metastases in 7 cases. Median disease-free survival was 23 months. Increasing tumor size and stage were related to risk of recurrence. The most common pattern of recurrence was local, suggesting that more aggressive initial RFA and adjuvant radiation may offer better outcomes. In another series with 31 consecutive patients with NSCLC deemed ineligible for resection, RFA was performed 38 times. Mean tumor size was 2.0 cm (range: 0.8–4.4 cm). Recurrence was confirmed radiographically after 32% of treatments. Two of these patients were successfully retreated for technical failures related to pneumothorax, and 3 underwent radiotherapy with stable disease. After mean follow-up of 17 months, 23 of the 31 patients were alive. Three patients died of metastatic disease, and 5 died of pneumonia remote from treatment. Two- and 4-year survivals were 78% and 47%, respectively. Local tumor progression appeared to be related to tumors larger than 3 cm.
Authors of 2 recent case series from Japan reported outcomes at median follow-up periods of 2 years. Yamakado et al. report on a series of 78 patients with 198 pulmonary metastases of colorectal cancer with median follow-up of 24.6 months. The respective 1-, 3-, and 5-year local tumor progression rates were 10.1% (95% CI: 2.9–17.3%), 20.6% (95% CI: 8.9–22.2%), and 20.6% (95% CI: 8.9–22.2%), respectively. The 1-, 3-, and 5-year survival rates were 83.9% (95% CI: 75.2–92.7%), 56.1% (95% CI: 41.7–70.5%), and 34.9% (95% CI: 18.0–51.9%), respectively, with median survival time of 38.0 months. Lack of extrapulmonary metastasis and normal carcinoembryonic antigen (CEA) level were significant independent prognostic factors. In the smaller series, 39 patients with unresectable pulmonary metastases of renal cell cancer were treated with RFA. Patients with 6 or fewer lung metastases measuring 6 cm or smaller that were confined in the lung, had all lung tumors ablated (curative ablation). Patients with extrapulmonary lesions, 7 or more lung tumors, or large tumors of greater than 6 cm, had mass reduction (palliative ablation). Overall survival rates in the curative and palliative groups were 100% versus 90% at 1 year, 100% versus 52% at 3 years, and 100% versus 52% at 5 years (p<0.05), respectively. Maximum lung tumor diameter was a significant prognostic factor. In the curative ablation group, the recurrence-free survival rates were 92% at 1 year, 23% at 3 years, and 23% at 5 years.

However, these results are compromised by the retrospective nature of the data; the potential confounding effects of undefined prior and adjuvant chemo- or radiotherapy; lack of histopathologic proof of treatment completeness; substantial patient and disease heterogeneity; and failure to separate overall survival rates according to disease.

Miscellaneous Tumors

Breast Tumors

Systematic Reviews

In 2010, Zhao and Wu conducted a systematic review of 38 studies on ablation techniques for breast cancer treatment published from 1994 to 2009. Nine of the studies reviewed focused on RFA. The RFA studies included small breast tumors ranging in size from 0.5–7 cm. Tumor resection was performed immediately after ablation or up to 4 weeks after RFA. Complete coagulation necrosis rates of 76% to 100% were reported. The results of this review suggest RFA for breast cancer tumors is feasible, but further studies with longer follow-up on survival, tumor recurrence, and cosmetic outcomes are needed to establish clinical efficacy.

In another 2010 review, Soukup and colleagues examined 17 studies on RFA for the treatment of breast tumors and found RFA is feasible and promising. However, while minimal adverse effects and complications occurred with breast RFA, the authors noted incomplete tumor ablation remains a concern.

Clinical Studies

In 2012, Wilson and colleagues reported on 73 patients with invasive breast cancer who had a lumpectomy followed
immediately by RFA to the lumpectomy bed. The average breast tumor size was 1.0 + 0.54 cm (range 0.2-2.6 cm) and follow-up averaged 51 months. Disease-free survival was 100%, 92% and 86% at 1-, 3- and 5-years, respectively. One patient had tumor recurrence within 5 cm of the lumpectomy site and 3 patients had ipsilateral breast recurrences.

In a 2011 Phase I/II study, 49 patients were treated with RFA for breast tumors (mean size 1.70 cm) followed immediately with surgical resection. Complete ablation was achieved in 30 patients (61%) by H&E staining and/or NADH diaphorase staining. Complete ablation increased to 83% in 24 patients with tumor size equal to or less than 2 cm in diameter. Adverse events related to the procedure included 3 muscle burns and 2 skin burns.

In 2009, Imoto et al. reported on a series of 30 patients with T1N0 breast cancer who had sentinel node biopsy followed by RFA and breast-conserving surgery. Twenty-six patients showed pathologic degenerative changes in tumor specimens with hematoxylin-eosin (H&E) staining, and, in 24 of 26 cases, tumor cell viability was diagnosed as negative by nicotinamide adenine dinucleotide (NADH) diaphorase staining. Two patients had skin burns and 7 had muscle burn related to RFA.

In a 2008 2-stage Phase II clinical trial, patients with histologically confirmed noninflammatory and 3 cm or less ipsilateral breast tumor recurrence were treated with RFA followed by mastectomy. The study was ended early because of insufficient efficacy of the technique tested.

Authors of a small (n=10) series, in 2009, in which tumor size and fat content were analyzed, concluded that “the fat content of small primary breast cancer could serve as a ‘heat sink’ and should be considered as a preventing factor of complete local tumor destruction by RF thermal ablation.”

Head and Neck Cancer

In 2011, Owen et al. reported on RFA for 13 patients with recurrent and/or unresectable head and neck cancer who failed curative treatment. Median patient survival was 127 days. While stable disease was reported in 8 patients after RFA, and quality-of-life scores improved, 3 deaths occurred (1 carotid hemorrhage and 2 strokes).

A case series of 14 patients with recurrent advanced head and neck malignancies was reported by Brook et al. Tumor targeting and electrode deployment was successful in all cases, and 4 of 6 patients who completed quality-of-life assessments showed improvement. Three major complications (in 27 applications, 11%) occurred 7 days to 2 weeks after the procedure. These included stroke, carotid artery rupture leading to death, and threatened carotid artery rupture with subsequent stroke.

Retrospective analysis of intraprocedural CT scans revealed that the retractable electrodes were within 1 cm of the carotid artery during ablation in these cases.

A case series showed palliative CT-guided RFA provided subjective improvement with regard to pain, appearance, and function in 12 patients who had recurrent and advanced head and neck malignancies and were not candidates for radiation or surgery. The procedure was deemed reasonably safe and feasible for this indication.
Thyroid Tumors

Systematic Reviews

In 2014 Fuller et al reported on a systematic review and meta-analysis of studies on RFA for benign thyroid tumors. Included in the review were 9 studies (5 observational studies, 4 randomized studies) totaling 306 treatments. After RFA, statistically significant improvements were reported in nodule size reduction (29.77 mL; 95% CI, -13.83 to -5.72), combined symptom improvement and cosmetic scores on the 0 to 6 scale (mean, -2.96; 95% CI, -2.66 to -3.25) and withdrawal from methimazole (odds ratio, 40.34; 95% CI, 7.78 to 209.09). Twelve adverse events were reported, 2 of which were considered significant but did not require hospitalization.

In 2012, the Korean Society of Thyroid Radiology (KSTR) developed consensus recommendations for RFA of thyroid tumors after a review of the literature found few controlled studies. The KSTR recommendations indicate RFA may be appropriate for the treatment of benign thyroid nodules, inoperable thyroid nodules, and recurrent thyroid cancers in the operation bed and lymph nodes. The KSTR recommendations also indicate RFA should not be used for primary thyroid cancers or follicular neoplasms citing no evidence of treatment benefit.

Clinical Studies

In 2013 Lim et al. reported on a case series of 111 patients treated with RFA for 126 benign nonfunctioning thyroid nodules. Patient follow-up was a mean duration of 49.4 ± 13.6 months. RFA significantly decreased the volume of the thyroid nodules from 9.8 ± 8.5 mL to 0.9 ± 3.3 mL (p<0.001) for a mean volume decrease of 93.4 ± 11.7%. Tumor recurrence occurred in 7 patients (5.6%). Complications occurred in 4 patients (3.6 %). Additionally, there was significant improvement in thyroid symptom scores (p<0.001).

Baek et al reported on a retrospective review of RFA for 1543 benign thyroid nodules in 1459 patients at 13 thyroid centers. Forty-eight (3.3%) complications occurred and included 20 major complications: voice changes (n=15), brachial plexus injury (n=1), tumor rupture (n=3), and permanent hypothyroidism (n=1). Twenty-eight minor complications included: hematoma (n=15), skin burn (n=4), and vomiting (n=9). One patient experienced permanent hypothyroidism while another required surgery.

In 2012, Huh et al reported on 30 patients randomized to receive either 1 or 2 RFA sessions for the treatment of benign thyroid nodules. Significant volume reduction occurred in each group of 15 patients after RFA. A single session of RFA was sufficient to reduce tumor volume and improve clinical symptoms in 12 patients (80%). Only 3 patients with nodules larger than 20 mL required an additional session of RFA.

A case series of 94 elderly subjects with solid or mainly solid benign thyroid nodules was reported by an Italian center. Thyroid nodule volume, compressive symptoms, and thyroid function were evaluated at baseline and 12 to 24 months after treatment. All thyroid nodules significantly decreased in size after RFA. Compressive symptoms improved in all patients and disappeared completely in 88% of patients. Hyperthyroidism resolved in most patients allowing methimazole therapy to be completely withdrawn in 79% of patients with pretoxic and toxic thyroid nodules.
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(100% in pretoxic and 53% with toxic thyroid nodules). The authors observe that RFA is particularly attractive for elderly people for whom surgery and radioiodine therapy are often contraindicated or ineffective.

A smaller series (n=33) also from Italy found similar outcomes in terms of reduction in compressive symptoms and improvement in thyroid function. Hyperfunction was fully controlled in 24% of patients and partially reduced in the others.

Other Miscellaneous Tumors

A large series in 2015 evaluated the effectiveness and safety of RFA for uterine myomas in a 10-year retrospective cohort study. From July 2001 to July 2011, a total of 1216 patients treated for uterine myomas were divided into 2 groups. Group A consisted of 476 premenopausal patients (average age 36±8 years) who had an average 1.7±0.9 myomas with average diameter of 4.5±1.5 cm. Group B consisted of 740 menopausal patients (average age, 48±4 years) with an average 2.6±1.3 myomas with average diameter of 5.0±2.5 cm. Patients were followed for a mean of 36±12 months. At 1, 3, 6, 12, and 24 months after RFA, the average diameters of myomas in group A were 3.8, 3.0, 2.7, 2.4, and 2.2 cm, respectively; 48% (227/476) of patients had residual tumor at 12 months after RFA. In group B, myoma diameters were 4.7, 3.7, 3.3, 2.3, and 2.3 cm, respectively; 59% (435/740) of patients had trace disease at 12 months after RFA. Three months after treatment, myoma volumes were significantly reduced in both the groups (p<0.01), although group B had a higher rate of residual tumor at 12 months after RFA than group A (p<0.05). Clinical symptoms and health-related quality of life were significantly improved after RFA in both groups. The postoperative recurrence rate of uterine myomas was significantly higher in group A at 10.7% (51/476) than group B at 2.4% (18/740; p<0.05).

One case series of 13 patients with adrenal neoplasms treated with RF ablation was identified. Eleven of the 13 lesions were treated successfully with RFA, defined by follow-up CT scans and normalization of preprocedural biochemical abnormalities.

A single-arm, retrospective, paired-comparison study evaluated the short-term efficacy of RFA in relationship to pain and functional impact in patients with unresectable, painful soft tissue neoplasms recalcitrant to conventional therapies. Patients had tumors located in a variety of sites including chest wall, pelvis, breast, perirectal, renal, aortocaval, retroperitoneal, and superficial soft tissues. All had exhausted conventional methods of palliation or experienced dose-limiting adverse effects from pain medication. Although not all Brief Pain Inventory scores were statistically significant, all mean scores trended down with increased time after ablation. Complications from RFA were minor or insignificant in all but 1 patient who had skin breakdown and infection of the ablated superficial tumor site.

Additional articles address the use of RFA in solid malignancies and in the pancreas. A recent systematic review examined studies of ablative therapies, including RFA, in patients with locally advanced pancreatic cancer. No RCTs were identified in this review, and conclusions are limited by the sparse evidence available on RFA in this setting.

Stereotactic radiofrequency thermocoagulation for epileptogenic hypothalamic hamartomas is described in a retrospective analysis of a series of 25 patients with gelastic seizures (a rare type of
seizure that involves a sudden burst of energy, usually in the form of laughing or crying). Other seizure types were exhibited in 22 patients (88.0%), precocious puberty in 8 (32.0%), behavioral disorder in 10 (40.0%), and mental retardation in 14 (56.0%). Gelastic seizures resolved in all but 2 patients. Complete seizure freedom was achieved in 19 patients (76.0%). These patients had disappearance of all seizure types and behavioral disorder and also demonstrated intellectual improvement.

Preliminary results of endoscopic RFA of rectosigmoid tumors have been described in a paper by Vavra et al. Twelve patients were treated with the Endoblate RFA device, with 10 patients having surgical resection after ablation. Histology of the resected specimens showed that, on average, 82% (range: 60-99%) of the tumor mass was destroyed in the ablation zone.

Small case series on RFA for colorectal and rectal carcinoma have demonstrated a debulking role for RFA. These case series do not allow comparison with available alternative treatments and are not covered.

Clinical Input Received through Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2009

In response to requests, input was received from one Physician Specialty Society and from two Academic Medical Centers while this policy was under review for February 2009. All reviewers supported the use of RFA in the treatment of painful bone metastases that have failed standard treatment and in the treatment of osteoid osteomas. The reviewers were divided with regards to the use of RFA for lung tumors, although several agreed that while it may be useful in a select population of patients, it should be used in the setting of a clinical trial. The reviewers were also split with regards to RFA in the treatment of renal tumors, with some supporting its use in a select population of patients. With the exception of one disagreement and one nonresponse, the reviewers agreed to the non-covered statement regarding the use of RFA in all other tumors outside the liver that are addressed in this policy.

2010

In response to requests, input was received from two physician specialty societies and four academic medical centers while this policy was under review in October 2010. The input was similar to that noted above (2009), except support for use in lung tumors was less (only one respondent indicated this was an option in tumors metastatic to lung). One respondent also indicated potential use for adrenal tumors. Comments on the specific role for RF ablation in renal tumors were again mixed.

Practice Guidelines and Position Statements

American College of Chest Physicians
The American College of Chest Physicians (ACCP) guidelines on the treatment of stage I and II non-small-cell lung cancer (NSCLC) indicate RFA has been used effectively in clinical stage I NSCLC. Therefore, in medically inoperable patients, peripheral NSCLC tumors less than 3 cm may be treated with RFA.62 ACCP also joined with the Society of Thoracic Surgeons to develop consensus guidelines on the treatment of high-risk patients with stage I NSCLC.63 These consensus guidelines indicate RFA is an alternative treatment option in patients who are not surgical candidates due to severe medical comorbidity.

National Comprehensive Cancer Network

National Comprehensive Cancer Network (NCCN) practice guidelines for the treatment of NSCLC state that “studies suggest that RFA may be an option for node-negative patients who either refuse surgery or cannot tolerate surgery” and that “optimal candidates for RFA include patients with an isolated peripheral lesion less than 3 cm.”64 Additionally, the guidelines note “RFA can be used for previously irradiated tissue and for palliation.” NCCN guidelines for colon cancer indicate that ablative techniques can be considered in those whose primary colon tumor was resected for cure when metastatic lung tumors are unresectable but amenable to complete ablation [category 2A]. NCCN practice guidelines for the treatment of colon cancer state that ablative techniques may be considered alone or in conjunction with resection. All original sites of disease need to be amenable to ablation or resection.

NCCN guidelines for thyroid carcinoma indicate ablative techniques such as radiofrequency may be considered for palliative resection of symptomatic distant metastases. Ablation may also be considered for asymptomatic distant metastases when there is progressive disease.

NCCN guidelines indicate RFA is a thermal ablation option for the treatment of kidney cancer in select patients with clinical stage T1 lesions who are not candidates for surgery. RFA is also an option in select patients such as elderly patients and others with competing health risks.

NCCN guidelines do not address the use of RFA in head and neck cancer.

NCCN guidelines do not address RFA in the management of breast cancer.

National Institute for Clinical Excellence

Guidance issued in 2004 indicates that “current evidence on the safety and efficacy of computed tomography (CT)–guided thermocoagulation of osteoid osteoma appears adequate to support its use, provided that the normal arrangements are in place for consent, audit and clinical governance.”

Guidance updated in 2010 indicates that “evidence on the safety and efficacy of percutaneous radiofrequency ablation (RFA) for renal cancer in the short and medium term appears adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit, and provided that patients are followed up in the long term.

Guidance on RFA for primary and secondary lung cancers issued in 2010 states, “[C]urrent evidence on the efficacy of percutaneous radiofrequency ablation (RFA) for primary or secondary lung cancers is adequate in terms of tumor control.” The National Institute for Clinical Excellence
Guidance also indicates RFA may “be used in patients with small, early-stage lung cancers or small numbers of lung metastases who are unsuitable for, or prefer not to undergo, surgery. It may also have a place in multi-modality treatment of more advanced primary lung cancers.”

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

VII. Important Reminder

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

VII. References


72. National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology, Thyroid Carcinoma.-v.1.2015


74. BCBSA Medical Reference Manual: Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors. #7.01.95. Last reviewed.09/2015