BlueCross BlueShield of Louisiana

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Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors

Policy # 00175
Original Effective Date: 08/24/2005
Current Effective Date: 12/18/2013

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: The use of Radiofrequency Ablation (RFA) of Primary or Metastatic Liver Tumors is addressed separately in medical policy 00182.

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Osteolytic Bone Metastases
Based on review of available data, the Company may consider radiofrequency ablation (RFA) to palliate pain in patients with osteolytic bone metastases who have failed or are poor candidates for standard treatments such as radiation or opioids to be **eligible for coverage**.

Osteoid Osteomas
Based on review of available data, the Company may consider radiofrequency ablation (RFA) to treat osteoid osteomas that cannot be managed successfully with medical treatment to be **eligible for coverage.**

Localized Renal Cell Carcinoma
Based on review of available data, the Company may consider radiofrequency ablation (RFA) to treat localized renal cell carcinoma (RCC) that is no more than 4 cm in size to be **eligible for coverage**.

Patient Selection Criteria
Coverage eligibility for radiofrequency ablation (RFA) to treat localized renal cell carcinoma (RCC) that is no more than 4 cm in size will be considered when EITHER of the following criteria is met:

- Preservation of kidney function is necessary (i.e., the patient has one kidney or renal insufficiency defined by a glomerular filtration rate [GFR] of less than 60 mL/min per m^2) and standard surgical approach (i.e., resection of renal tissue) is likely to substantially worsen kidney function; or
- Patient is not considered a surgical candidate.

Isolated Peripheral Non-Small Cell Lung Cancer Lesion
Based on review of available data, the Company may consider radiofrequency ablation (RFA) to treat an isolated peripheral non-small cell lung cancer (NSCLC) lesion that is no more than 3 cm in size to be **eligible for coverage**.

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Patient Selection Criteria
Coverage eligibility for radiofrequency ablation (RFA) to treat an isolated peripheral non-small cell lung cancer (NSCLC) lesion that is no more than 3 cm in size will be considered when ALL of the following criteria are met:

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

Malignant Non-Pulmonary Tumor(s) Metastatic to the Lung
Based on review of available data, the Company may consider radiofrequency ablation (RFA) to treat malignant non-pulmonary tumor(s) metastatic to the lung that are no more than 3 cm in size to be **eligible for coverage**.

Patient Selection Criteria
Coverage eligibility for radiofrequency ablation (RFA) 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:

- 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; and
- 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; and
- No more than 3 tumors per lung should be ablated; and
- Tumors should be amenable to complete ablation; and
- Twelve months should elapse before a repeat ablation is considered.

When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers radiofrequency ablation (RFA) to be **investigational*** as a technique for ablation of:

- Breast tumors;
- Lung cancer not meeting the criteria above;
- Renal cell cancer not meeting criteria above;
- Osteoid osteomas that can be managed with medical treatment;
- Painful bony metastases as initial treatment; and
- 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.

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Background/Overview

In 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.

Radiofrequency ablation 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). Radiofrequency ablation 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.

Radiofrequency ablation was initially developed to treat inoperable tumors of the liver. 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).

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.

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 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. Radiofrequency ablation 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.

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. Radiofrequency ablation has been investigated as another alternative for palliating pain from bone metastases.

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Pulmonary Tumors
Surgery is the current treatment of choice in patients with stage 1 primary 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 as 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 2 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.

Stereotactic radiation therapy (SRT) has gained more widespread use, as it is a high-precision mode of therapy that allows for delivery of very high doses of radiation. Two- to 3-year local control rates of stage 1 NSCLC with SRT have ranged from 80–95%. Many reports on outcomes with SRT have been in patients unfit to undergo surgery, introducing a large selection bias compared with that in surgery. However, one study that reported on nearly 100 patients who refused surgery (versus being deemed unfit) had a 5-year OS rate of 71% with SRT to treat stage 1 NSCLC, a rate that is at least equivalent to surgical outcome.

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

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).

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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
The FDA issued a statement September 24, 2008 concerning the regulatory status of RFA. The FDA has cleared RFA devices for the general indication of soft tissue cutting, coagulation, and ablation by thermal

coagulation necrosis. Some RFA devices have been cleared for additional specific treatment indications, including partial or complete ablation of nonresectable liver lesions and palliation of pain associated with metastatic lesions involving bone. The FDA has not cleared any RFA devices for the specific treatment indication of partial or complete ablation of lung tumors, citing lack of sufficient clinical data to establish safety and effectiveness for this purpose. The FDA has received reports of death and serious injuries associated with the use of RFA devices in the treatment of lung tumors.

Rationale/Source

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 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 $p \leq 0.0005$). 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.

Summary

Case series have included 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. Therefore, the use of RFA as palliative therapy in patients with painful metastatic bone lesions may be considered medically necessary.

Because data are unavailable on use of RFA as initial therapy for pain from bone metastases, this indication remains investigational.

Neither setting is addressed in the National Comprehensive Cancer Network (NCCN) guidelines for the treatment of bone cancers.

National Cancer Institute (NCI) Clinical Trials Database (PDQ®)‡

A search of the NCI clinical trial database at ClinicalTrials.gov returned no current trials on the use of RFA for bone metastases.

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Osteoid Tumors
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 an 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 MRI, and 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.

Summary
There are no randomized trials for this indication, however, uncontrolled studies have demonstrated RFA can provide adequate pain relief with minimal complications. Therefore, the use of RFA for the treatment of osteoid osteomas that cannot be successfully treated with medical treatment may be considered medically necessary.

National Institute for Clinical Excellence (NICE)
Guidance issued in 2004 indicates that "current evidence on the safety and efficacy of 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."

National Cancer Institute Clinical Trials Database (PDQ)
A search of the online NCI clinical trial database at ClinicalTrials.gov returned no current trials on the use of RFA in osteoid tumors.

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Renal Tumors
The outcomes of RFA procedures in many patients have been described in numerous uncontrolled studies. The characteristics of the patients and RFA procedures varied widely within and across the studies in terms of tumor type (e.g., exophytic, parenchymal, central, with or without history of von Hippel-Lindau disease), tumor size (from smaller than 1 cm to larger than 8 cm), length of follow-up (from less than 1 month to 48 months), imaging modality used for guidance, and reason for using RFA.

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: 2–4.3 cm) in the RFA group and 2.5 cm (range: 2–4.2 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% confidence interval [CI]: 0.86-0.93) and 89% (95% 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 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 posttreatment 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. Additionally, the article points out that the longest

average follow-up of published studies of RFA and kidney tumors is 28 months and that long-term follow-up data are necessary to validate the use of this technique.

Stern and colleagues retrospectively compared patients with stage T1a renal tumors, confirmed by pathology to be 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.

Summary
Based on the scientific data (large numbers of patients treated with follow-up) and the clinical input (see below) received, RFA of small (i.e., 4 cm or less) renal cancers may be considered medically necessary in those 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.

National Comprehensive Cancer Network (NCCN) Guidelines
National Comprehensive Cancer Network 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. Radiofrequency ablation is also an option in select patients such as elderly patients and others with competing health risks.

National Institute for Clinical Excellence (NICE)
Guidance updated in 2010 indicates that “evidence on the safety and efficacy of percutaneous 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.

National Cancer Institute Clinical Trials Database (PDQ)
A search of the online clinical trials database at ClinicalTrials.org on September 21, 2013 identified one ongoing randomized controlled trial (RCT). In NCT01838720, 90 patients will be randomized to compare laparoscopic RFA to laparoscopic partial nephrectomy for stage T1a RCC tumor removal.

Pulmonary Tumors
Radiofrequency ablation has been used to treat pulmonary tumors in many studies. Numerous systematic reviews have been published and have found the available evidence on RFA for pulmonary tumors is lacking and consists primarily of uncontrolled studies. In a 2013, the Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Review of local nonsurgical therapies for stage I NSCLC, 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 stereotactic radiotherapy (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%) with 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 OS, 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. The authors observed that RFA for the treatment of lung tumors is promising, noting better outcomes with RFA than traditional external-beam radiotherapy and RFA outcomes comparable to surgery but with lower rates of procedural mortality (0.21% vs. 1%, respectively). Additionally, repeated RFA procedures can be performed without reducing lung function. The authors acknowledged the current evidence is limited to case series and indicated further prospective studies are needed to compare RFA to other local treatment options.

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 NSCLC. The authors found OS 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.

In 2010, Zemlyak and colleagues prospectively compared 3 treatments for medically inoperable patients with stage I 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 with NSCLC was 70% at 1 year (95% 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. The authors concluded that RFA yields high proportions of sustained complete response in selected patients and RCTs that compare RFA with standard nonsurgical treatment options are warranted. Comparison of patient survival rates with those from other studies in which different modalities were used are unreliable due to the heterogeneity of the study population and the severe pulmonary impairment and significant comorbidities of the patients in this study.

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 RFA treatment sessions for 100 patients with inoperable lung tumors. In this study, there was no postprocedural 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. The authors concluded that RFA for lung tumors could be considered safe and technically feasible, with an acceptable incidence of complications.

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 posttreatment 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. The authors concluded that RFA of inoperable early-stage lung cancer in carefully selected patients yields encouraging results and that CT and positron emission tomography (PET) need further validation for the early identification of local tumor progression following RFA.

Authors of 2 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 for 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 OS rates according to disease.

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Summary
While 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. Although complications have been reported with the use of RFA in the lung, 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.

American College of Chest Physicians (ACCP)
The ACCP guidelines on the treatment of stage I and II non-small-cell lung cancer indicate RFA has been used effectively in clinical stage 1 NSCLC. Therefore, in medically inoperable patients, peripheral NSCLC tumors less than 3 cm may be treated with RFA. The ACCP also joined with the Society of Thoracic Surgeons to develop consensus guidelines on the treatment of high-risk patients with stage I NSCLC. 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 Guidelines
National Comprehensive Cancer Network 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.” Additionally, the NCCN guidelines note “RFA can be used for previously irradiated tissue and for palliation.” The 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].

National Institute for Clinical Excellence
Guidance on RFA for primary and secondary lung cancers issued in 2010 states, “[C]urrent evidence on the efficacy of percutaneous RFA for primary or secondary lung cancers is adequate in terms of tumor control.” The NICE 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.”

National Cancer Institute Clinical Trials Database (PDQ)
In a search of the clinical trials database online at ClinicalTrials.gov, 3 ongoing, nonrandomized studies of RFA and lung tumors were identified. Radiofrequency ablation will be evaluated for resectable colorectal lung metastasis (NCT00776399). Radiofrequency ablation combined with stereotactic body radiotherapy will be evaluated for lung tumors near the central airway (NCT01051037). And an additional study assessing short- and long-term outcomes after RFA of pulmonary malignancies in patients who are not candidates for surgical resection is ongoing (NCT00280189).

Breast Tumors
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 authors concluded RFA for breast cancer tumors is feasible, but further studies with longer follow-up on survival, tumor recurrence, and cosmetic outcomes are needed. 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.

The following are examples of published studies on RFA for breast tumors. 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 $\pm$ 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 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.” 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.

Summary

Studies on RFA for breast tumors have 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 to 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 to conventional breast-conserving treatment. Therefore, RFA in the treatment of breast cancer is considered investigational.

National Comprehensive Cancer Network Guidelines

National Comprehensive Cancer Network guidelines do not address RFA in the management of breast cancer.

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National Cancer Institute Clinical Trials Database (PDQ)
A search of the clinical trials database online at ClinicalTrials.gov identified no randomized studies on RFA for breast cancer. One nonrandomized study will evaluate outcomes of RFA after breast cancer lumpectomy in 250 patients (NCT01153035). One other ongoing (but no longer recruiting) Phase I/II NCI clinical trial was identified, including a pilot study of RFA to breast cancer lumpectomy sites to achieve negative margins without removing large volumes of tissue (NCT00571987).

Head and Neck Cancer
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, but further study is needed.

A case series of RFA for 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.

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).

Summary
The evidence for RFA in head and neck tumors is limited to small case series. While RFA may have a role in palliation, complications are common and severe. Therefore, RFA for the treatment of head and neck tumors is considered investigational.

National Comprehensive Cancer Network Guidelines
The NCCN guidelines do not address the use of RFA in head and neck cancer.

National Cancer Institute Clinical Trials Database (PDQ)
A search of the NCI clinical trial database at ClinicalTrials.gov returned no current trials on the use of RFA in head and neck cancer.

Thyroid Tumors
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 ($p < 0.001$).

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 (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.

In 2012, Huh and colleagues 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. Baek et al. reported on a retrospective review of RFA for 1,543 benign thyroid nodules in 1,459 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, 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.

Summary

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. Therefore, RFA for the treatment of thyroid tumors is considered investigational.

National Cancer Institute Clinical Trials Database (PDQ)

A search of the NCI clinical trial database online at ClinicalTrials.gov returned one current trial on the use of RFA in thyroid tumors. In NCT01778400, 50 patients will be randomized to compare RFA to ethanol injections for thyroid tumors.

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National Comprehensive Cancer Network Guidelines
The NCCN guidelines for thyroid carcinoma indicate ablation 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.

Miscellaneous Neoplasms
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.

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.

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.

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 investigational in the policy statement.

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.

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2009
In response to requests, input was received from 1 Physician Specialty Society (4 reviews) and from 2 Academic Medical Centers (3 reviews) 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 1 disagreement and 1 nonresponse, the reviewers agreed to the investigational 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 2 physician specialty societies (4 reviewers) and 2 academic medical centers (4 reviewers) 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 1 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 RFA in renal tumors were again mixed.

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Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors

Policy # 00175
Original Effective Date: 08/24/2005
Current Effective Date: 12/18/2013

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2012 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	20982, 32998, 50542, 50592, 76940, 77013, 77022
HCPCS	No code
ICD-9 Diagnosis	162.9, 174.0 thru 174.9, 189.0 thru 189.9, 193, 213.0 thru 213.9
ICD-9 Procedure	32.29, 55.32 thru 55.35, 77.6, 85.20

Policy History

Original Effective Date: 08/24/2005
Current Effective Date: 12/18/2013

07/13/2005	Medical Director review
07/19/2005	Medical Policy Committee review
08/24/2005	Managed Care Advisory Council approval
07/07/2006	Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
08/08/2006	Medical Director review
08/09/2006	Medical Policy Committee approval.
07/10/2007	Medical Director review
07/18/2007	Medical Policy Committee approval. Policy Statement added for osteoid osteoma and rationale/source updated.
07/02/2008	Medical Director review
07/16/2008	Medical Policy Committee approval. Coverage eligibility unchanged.
07/02/2009	Medical Director review
07/22/2009	Medical Policy Committee approval. Coverage statement added to indicate that use of radiofrequency ablation as treatment of osteoid osteomas that cannot be managed successfully with medical treatment may be considered eligible for coverage. Coverage statement added that treatment of localized renal cell carcinoma no more than 4cm in size may be considered eligible for

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	coverage when specific criteria are met. Added that radiofrequency ablation for the treatment of osteoid osteomas that can be managed with medical treatment is considered to be investigational.
08/05/2010	Medical Policy Committee review
08/18/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/04/2011	Medical Policy Committee review
08/17/2011	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/02/2012	Medical Policy Committee review
08/15/2012	Medical Policy Implementation Committee approval. Added options for primary and metastatic pulmonary tumors to be eligible for coverage with criteria.
12/12/2013	Medical Policy Committee review
12/18/2013	Medical Policy Implementation Committee approval. Reformatted investigational statement and added thyroid as investigational.

Next Scheduled Review Date: 12/2014

*****Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. in accordance with nationally accepted standards of medical practice;
B. clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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