

Radiofrequency Ablation of Tumors (RFA)

Effective: February 1, 2019

Next Review: November 2019

Last Review: January 2019

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Radiofrequency ablation kills cells using the heat produced by radiofrequency energy delivered into the tumor via a probe.

MEDICAL POLICY CRITERIA

Note: This policy does not address liver tumors (primary or metastatic). See Cross References.

- I. Radiofrequency ablation may be considered **medically necessary** to treat tumors when one or more of the following criteria are met:
 - A. Localized renal cell carcinoma that is no more than 4 cm in size when one or both of the following criteria are met:
 1. 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 m²) and standard surgical approach (i.e., resection of renal tissue) is likely to substantially worsen kidney function; or
 2. Patient is not considered a surgical candidate.

- B. Osteoid osteomas that are unresponsive to initial medical treatment
 - C. To palliate pain in patients with osteolytic bone metastases who have failed or are poor candidates for standard treatments such as radiation or opioids
 - D. Isolated peripheral non-small cell lung cancer (NSCLC) lesion that is no more than 3 cm in size when both 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; and
 - 2. Tumor is located at least 1 cm from the trachea, main bronchi, esophagus, aorta, aortic arch branches, pulmonary artery and the heart.
 - E. Malignant non-pulmonary tumor(s) metastatic to the lung that are no more than 3 cm in size when all of the following criteria (1. – 3.) are met:
 - 1. 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
 - 2. There is no evidence of extrapulmonary metastases; and
 - 3. The tumor is located at least 1 cm from the trachea, main bronchi, esophagus, aorta, aortic arch branches, pulmonary artery and the heart.
 - F. Renal angiomyolipomas when one or more of the following criteria are met:
 - 1. Symptomatic lesion (e.g., hemorrhage), or
 - 2. Asymptomatic lesion larger than 4 cm.
- II. Radiofrequency ablation is considered **investigational** as a technique for ablating all other benign or malignant tumors (see Policy Guidelines).

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

POLICY GUIDELINES

REQUIRED DOCUMENTATION

It is critical that the list of information below is submitted for review to determine if the policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome.

1. Specific description of the tumor(s) targeted for treatment including the following:
 - Tumor type (primary vs. metastatic; primary tumor type)
 - The location of tumor(s)
 - The number and size(s) of lesion(s) being treated
2. Rationale for the determination that the patient is not a surgical candidate or the tumor is unresectable
3. Whether the goal of treatment is curative or palliative
4. Comorbidities and any contraindicated treatments (e.g., surgery; radiation therapy)
5. Prior treatments, if any, and tumor response

6. Documentation of whether this treatment is to preserve organ function

NEUROENDOCRINE TUMORS

Neuroendocrine tumors are rare, slow-growing, hormone-secreting tumors that may occur in numerous locations in the body.^[1] Neuroendocrine tumors include the following:

- Carcinoid Tumors
- Islet Cell Tumors (also known as Pancreatic Endocrine Tumors)
- Neuroendocrine Unknown Primary
- Adrenal Gland Tumors
- Pheochromocytoma/paraganglioma
- Poorly Differentiated (High Grade or Anaplastic)/Small Cell
- Multiple Endocrine Neoplasia, Type 1 (also known as MEN-1 syndrome or Wermer's syndrome)
- Multiple Endocrine Neoplasia, Type 2 a or b (also known as pheochromocytoma and amyloid producing medullary thyroid carcinoma, PTC syndrome, or Sipple syndrome)

Neuroendocrine tumors may also be referred to by their location (e.g., pulmonary neuroendocrine tumors; gastroenteropancreatic neuroendocrine tumors).

Some appendiceal carcinoids, also called adenocarcinoids, goblet cell carcinoids, or crypt cell carcinoids, have mixed histology, including elements of adenocarcinoma. While these biphasic tumors have both neuroendocrine and adenocarcinoma components, the National Comprehensive Cancer Network (NCCN) recommends they be managed according to colon cancer guidelines.

INVESTIGATIONAL INDICATIONS

Radiofrequency ablation is considered investigational as a technique for ablating all other benign or malignant tumors that do not meet the policy criteria above including but not limited to breast tumors, initial treatment of osteoid osteomas, initial treatment of painful bony metastases, and all other primary or metastatic lung (pulmonary) tumors that do not meet medical necessity.

CROSS REFERENCES

1. [Radioembolization for Primary and Metastatic Tumors of the Liver](#), Medicine, Policy No. 140
2. [Cryosurgical Ablation of Miscellaneous Solid Tumors](#), Surgery, Policy No. 132
3. [Magnetic Resonance \(MR\) Guided Focused Ultrasound \(MRgFUS\) and High Intensity Focused Ultrasound \(HIFU\) Ablation](#), Surgery, Policy No. 139
4. [Microwave Tumor Ablation](#), Surgery, Policy No. 189
5. [Ablation of Primary and Metastatic Liver Tumors](#), Surgery, Policy No. 204

BACKGROUND

Radiofrequency ablation (RFA) was initially developed to treat inoperable tumors of the liver (see Cross References). Recently, studies have reported on the use of RFA to treat 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 (eg, preserving normal organ tissue, decreasing morbidity, decreasing length of hospitalization).

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 cancerous tumors. The effective volume of RFA depends on the frequency and duration of applied current, local tissue characteristics, and probe configuration (eg, single vs multiple tips). RFA can be performed as an open surgical procedure, laparoscopically or percutaneously, with ultrasound or computed tomography 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), and secondary tumors (if cells seed during probe removal).

REGULATORY ISSUES

The U.S. Food and Drug Administration (FDA) issued the following statement September 24, 2008 concerning the regulatory status of radiofrequency ablation.^[2] “The FDA has cleared RF ablation devices for the general indication of soft tissue cutting, coagulation, and ablation by thermal coagulation necrosis. Some RF ablation 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 RF ablation 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 RF ablation devices in the treatment of lung tumors.”

EVIDENCE SUMMARY

RENAL CELL CARCINOMA

BACKGROUND

Radical nephrectomy, partial nephrectomy, or nephron-sparing surgery remains the principal treatments of renal cell carcinoma (RCC).

RFA may be considered a treatment option when surgical excision is not an option such as the following:

- When preservation of renal function is necessary (e.g., in patients with marginal renal function, a solitary kidney, bilateral tumors)
- In patients with comorbidities that would render them unfit for surgery.
- In patients at high risk of developing additional renal cancers (as in von Hippel-Lindau disease).

SYSTEMATIC REVIEWS

An AHRQ Evidence Report, most recently amended in 2016, included thermal ablation (RFA or cryoablation; surgical or image-guided) as an available management strategies for stage I or II RCC.^[3] The report noted that better oncologic outcomes were believed to be achieved with

partial or radical nephrectomy; however, these procedures were associated with significantly higher complication rates than thermal ablation or active surveillance.

In 2014 Wang published a meta-analysis of 145 studies published through July 2013 comparing effectiveness and complications of radiofrequency ablation and partial nephrectomy (PN) for treatment of stage T1 renal tumors.^[4] 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, $p < 0.001$). Several limitations to this meta-analysis were discussed in the article. These included the limited follow-up duration of the included studies and the unavailability of the original study data. Despite the limitations, the data was sufficient for the authors to conclude that both RFA and PN were viable in terms of short-term outcomes and low complication rates. RFA showed a higher risk of local tumor progression but lower complication rates.

In 2014 Katsanos reviewed one RCT and five cohort studies (N=587) on thermal ablation (five studies with RFA^[5-9] and 1 study with microwave^[10]) or nephrectomy for small renal tumors with a mean size of 2.5 cm.^[11] 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 ablation patients than nephrectomy (7.4 vs 11.1 %; pooled RR=0.55; 95 % CI, 0.31 to 0.97; $p = 0.04$). RCT data was insufficient to determine any clear advantage of any one ablation method over the others. The systematic review is subject to the limitations in the included trials, such as the small group sizes, lack of randomized controlled trials, and inconsistent reporting of overall survival data.

RANDOMIZED CONTROLLED TRIALS

Since the systematic reviews reported above, no additional randomized controlled trials evaluating RFA as a treatment for renal cell carcinoma were identified.

NONRANDOMIZED STUDIES

Published studies have consistently reported fairly high success rates at up to six years follow-up; two to five re-ablation sessions were often necessary to achieve 95% tumor necrosis.^[7,12-34] Numerous case series, while unreliable, consistently suggest that the benefits of RFA outweigh the risks in patients for whom nephrectomy is not possible. Current studies suggest that physician specialty (i.e., interventional radiology, urology) and experience, and procedure approach (i.e., percutaneous, open, laparoscopic) may impact tumor recurrence and patient survival outcomes, and authors have recommended further study on these variables.

ADVERSE EVENTS

Reported complication rates have been low.^[7,12-33,35] Complications reported in the literature to date have included the following:

- Perinephric hematomas
- Hemorrhage
- Ureteral strictures

- Percutaneous urinary fistula
- Appendiceal perforation

BREAST TUMORS

BACKGROUND

The standard treatment for breast cancer is surgical excision by lumpectomy or mastectomy. Adjuvant radiation therapy, chemotherapy, and/or hormone therapy may also be used. If treated, fibroadenomas, benign tumors of the breast, are typically surgically excised.

SYSTEMATIC REVIEWS

In 2016, Chen reported results from a meta-analysis of clinical trials assessing the effect of radiofrequency ablation for breast cancer.^[36] The authors pooled data from fifteen nonrandomized studies that were published between 2001 and 2012. Of the 15 studies, eight studies reported that the tumor size was <2 cm, five studies reported <3 cm, and the remaining two studies reported <5 cm; eleven studies reported complete ablation rate, from which pooled estimates were 89% (95% CI: 85-93%) of patients receiving RFA achieved a complete ablation. Five studies reported recurrence rate, from which pooled data suggest no local recurrence at a maximum follow-up of 76 months. A statistical test of publication bias showed no potential publication bias ($Z=0.78$, $P=0.436$). The analyses were limited by small sample size of the included studies, and heterogeneity in patient selection; the authors conclude large, well-designed studies are necessary.

In 2010, Zhao conducted a systematic review of 38 studies on ablation techniques for breast cancer treatment published from 1994 to 2009.^[37] Nine of the studies reviewed focused on RFA for 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. These studies were limited to feasibility or pilot studies that were difficult to compare due to heterogeneous patient and tumor characteristics and energy sources. In addition, the studies were conducted in the research setting rather than in clinical practice. The authors concluded that RFA for breast cancer tumors was feasible but further studies with longer follow-up on survival, tumor recurrence and cosmetic outcomes are needed.

Similarly, another 2010 review of 17 studies by Soukup reported that RFA for the treatment of breast tumors was feasible and promising.^[38] However, while minimal adverse effects and complications occurred with breast RFA, the authors noted that incomplete tumor ablation remained a concern. Additional studies of health outcomes and refinement of the procedure were recommended.

RANDOMIZED CONTROLLED TRIALS

No randomized controlled trials of RFA as a treatment for breast tumors were identified.

NONRANDOMIZED STUDIES

Current published evidence is limited to preliminary nonrandomized pilot and feasibility studies with small numbers of patients.^[39-53] These studies preclude conclusions due to methodologic

limitations such as non-random allocation of treatment and a lack of appropriate comparison groups.

The bulk of the published studies measured secondary outcomes such as tissue analysis for viable cancer cells less than one month following RFA. No long-term follow-up data has been reported on local control and survival rates for RFA of breast cancer compared with conventional breast-conserving treatment. Small study populations limit the ability to rule out the role of chance as an explanation of study findings. The heterogeneity of the patient selection criteria between studies limits meaningful comparison of outcomes. The role of various patient characteristics (e.g., tumor size and location; number of tumors) cannot be ruled out as an explanation for study findings.

LUNG (PULMONARY) TUMORS

BACKGROUND

Surgery is the preferred treatment for primary non-small cell lung carcinoma (NSCLC). Patients with early stage NSCLC who are not surgical candidates may be candidates for radiation treatment with curative intent. RFA is being investigated as a treatment of small primary lung cancers or lung metastases in patients who are not surgical candidates.

SYSTEMATIC REVIEWS

In a 2013 Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Review on local nonsurgical therapies for stage I non–small-cell lung cancer (NSCLC), no comparative RFA studies were identified.^[54] 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, surgical excision 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.^[55]

A 2011 systematic review also reported low quality evidence consisting of nonrandomized observational case series with no control group. The review included 46 studies with a total of 2,905 ablations in 1,584 patients.^[56] The mean tumor size of 2.8 ± 1.0 cm. Local recurrence occurred in 282 cases (12.2%) and ranged from 0% to 64% as reported in 24 studies. Overall survival rates ranged from 25% to 100% with a mean of 59.4% as reported in 21 studies with a mean of 17.7 ± 12.4 months follow-up. 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, pleural effusion and pain. Mortality related to the RFA procedure was 0.21% overall. The authors concluded RFA for the treatment of lung tumors demonstrated promise but that higher quality studies comparing RFA to other local treatment options “are urgently needed.”

In a 2012 review of evidence from 16 studies, Bilal compared RFA to stereotactic ablative radiotherapy (SABR) in patients with inoperable early stage non-small cell lung cancer (NSCLC).^[57] 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%). 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.

RANDOMIZED CONTROLLED TRIALS

No randomized controlled trials of RFA as a treatment for pulmonary tumors were identified.

NONRANDOMIZED STUDIES

Current studies consist of small case series, retrospective reviews, or uncontrolled cohort studies which focused primarily on technical feasibility and initial tumor response.^[58-90]

One larger nonrandomized case series was published in 2011. Huang prospectively followed 329 consecutive patients treated with RFA for lung tumors.^[91] Complications were experienced by 34.3% (113) patients and was 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 < 4 cm but became significant in tumors > 4 cm.

In 2015 de Baere review of a database from two cancer centers that included all consecutive patients (N=566) with lung metastases treated with RFA.^[92] Median follow-up was 35.5 months (range 20-53 months) with 235 patients followed for more than 2 years. During follow-up, 176 patients died, of which 112 had progression of their lung tumor disease. Disease progression was also found in 227 of the 390 patients who were alive at last follow-up. Four-year local efficacy was 89% and lung disease control was 44.1%. Median overall survival was 62 months. Limitations of this study included the lack of a control group, and the lack of consideration of the impact of adjuvant chemotherapy.

Study quality concerns include lack of long-term follow-up; significant interstudy heterogeneity in terms of study design, patient populations and RFA methods used; and, non-uniformity of reporting and efficacy scoring criteria. These differences limit meaningful comparison between studies because they may significantly impact study findings.

ADVERSE EVENTS

Acute, delayed or recurrent pneumothorax is the most commonly reported complication of lung RFA for primary or metastatic tumors (30-56% of treatment sessions).^[83,91,93-96] Most cases resolved without chest tube placement.

Other complications reported in the literature to date are considered uncommon and include the following.^[95-100]

1. Pleural effusion
2. Intrathoracic hemorrhage with or without hemothorax
3. Hemoptysis
4. Pneumonia
5. Fever
6. Post procedure chest pain
7. Exacerbation of interstitial pneumonia
8. Bronchopleural fistula
9. Seeding of the needle tract with cancer cells
10. Lung inflammation; aseptic pleuritis

11. Infection or abscess
12. Cough
13. Subcutaneous emphysema
14. Pain duration ablation procedure
15. Pleuritic chest pain
16. Pneumonitis
17. Stellate ganglion injury
18. Brachial plexus injury
19. Death

OSTEIOD OSTEOMAS

BACKGROUND

Osteomas usually heal spontaneously in three to four years and standard initial treatment includes medical management with NSAIDs. Invasive procedures including open surgery, laser photocoagulation, radiofrequency ablation, or core drill excision may be necessary if symptoms cannot be managed with NSAIDs.

SYSTEMATIC REVIEWS

Lanza (2014) reported on a systematic review of various ablative techniques for osteoid osteomas.^[101] Included in the review were 23 articles on RFA, 3 on interstitial laser ablation, and one with a combination of ablation techniques, totaling 27 articles (total N=1772 patients). The mean technical success was 100% and clinical success, defined as being pain-free, ranged from 94% to 98%, depending on the 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.

RANDOMIZED CONTROLLED TRIALS

No randomized controlled trials of RFA as a treatment for osteoid osteomas were identified.

NONRANDOMIZED STUDIES

Numerous nonrandomized uncontrolled case series have consistently suggested that the benefits of RFA outweigh the risks in patients who require treatment due to failed response to nonsurgical treatments.^[102-109]

SECTION SUMMARY

Despite the weaknesses in the published clinical evidence, RFA of osteomas has become a standard of care for osteomas that have failed standard treatments. This was based on the lower morbidity and quicker recovery time associated with the procedure compared with open surgery. The risk of osteoma recurrence with RFA is 5–10%; recurrent tumors can be retreated with RFA. There are minimal clinical trial data on the risks and benefits of RFA as initial treatment of osteoid tumors. Since most of these tumors heal spontaneously with medical treatment, the necessity of surgical intervention as initial treatment is unclear.

PALLIATION OF PAIN FROM BONE METASTASES

BACKGROUND

External beam irradiation is often the initial palliative therapy for osteolytic bone metastases. However, pain from bone metastases is refractory to radiation therapy in 20% to 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 may be considered another alternative for palliating pain from bone metastases.

SYSTEMATIC REVIEWS

Lanza reported on a systematic review of various ablative techniques for osteoid osteomas in 2014.^[101] Included in the review were 23 articles on RFA, 3 on interstitial laser ablation, and one with a combination of ablation techniques, totaling 27 articles (total N=1772 patients). The 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.

RANDOMIZED CONTROLLED TRIALS

No randomized controlled trials of RFA as a treatment for palliation of pain from bone metastases were identified.

NONRANDOMIZED STUDIES

Current evidence is limited to data from small, poorly designed case series.^[110-114] However, though small and uncontrolled, available studies consistently reported significant improvement in pain following RFA in patients who failed or were poor candidates for standard treatments. Clinical trial data is lacking for use of RFA as an alternative to conventional techniques for initial treatment of painful bony metastases.

ANGIOMYOLIPOMA

BACKGROUND

Angiomyolipomas (AMLs) or angiomyolipomata are rare benign tumors that contain blood vessels, smooth muscle, and fat. They are usually associated with the kidneys but may also be in the liver or other locations. They are more frequently seen in patients with tuberous sclerosis complex (TSC). These lesions are usually asymptomatic but may hemorrhage, particularly if large (4 cm or larger). Treatment consists of surveillance as long as the lesion remains small and asymptomatic. Treatment or prevention of hemorrhage may include surgical resection, arterial embolization, or laparoscopic or percutaneous ablation.

PUBLISHED STUDIES

Due to the rare nature of these tumors, there is limited published evidence on the tumor management.^[115-120] The current studies have significant methodological limitations including retrospective records review, small size (n=4-32), heterogeneity of patients and treatment modalities, and short-term follow-up. However, the available studies consistently reported low rates of complications and high rates of successful ablation, generally without recurrence at mean follow-up ranging between 9 and 45 months. Some larger tumors (>3.5 cm) required two RFA sessions. Minor complications included transient perinephric hematoma, intercostal nerve transection. A patient in one early study developed a small skin metastasis at the electrode insertion site which was resected and did not recur.

SECTION SUMMARY

Because this is a rare tumor that is often identified incidentally and may not require treatment, it is unlikely that large randomized controlled trials or comparative studies will become available. Due to the risk of potentially life-threatening hemorrhage in large (≥ 4 cm) AMLs and the low rate of adverse effects, treatment of symptomatic or large lesions may be warranted.

HEAD AND NECK TUMORS

BACKGROUND

Tumors of the head and neck arise in the lip, oral cavity, pharynx, larynx, paranasal sinuses and salivary glands. Treatment depends on the location and extent of the disease.^[121] Standard treatment for patients with early-stage disease (stage I or II) is single-modality with surgery or radiation therapy. The two modalities result in similar survival. Combined modality therapy is required for locally advanced disease. In patients with recurrent head and neck cancer, 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.

SYSTEMATIC REVIEWS RANDOMIZED CONTROLLED TRIALS

No systematic reviews or randomized trials evaluating the safety and effectiveness of RFA for treatment of head and neck tumors were identified.

NONRANDOMIZED STUDIES

Current published evidence is limited to poorly designed case series, feasibility, and retrospective studies that are considered unreliable due to lack of a control group for comparison and lack of randomization to control for bias.^[122-126]

In addition to these methodological limitations, prospective case series included small numbers of patients. Small study populations limit the ability to rule out the role of chance as an explanation of study findings.

ADVERSE EVENTS

Complications and adverse events are reported to be uncommon, but are often severe. They are generally related to burning of local soft tissue (e.g., fistula formation).^[122-125]

THYROID TUMORS

BACKGROUND

Thyroid carcinoma is uncommon, with a lifetime risk of being diagnosed with thyroid carcinoma less than 1%. Thyroid carcinoma occurs 2 to 3 times more often in women than men. The main histological types of thyroid carcinoma include: 1) differentiated (including papillary, follicular, and Hürthle); 2) medullary; 3) anaplastic (aggressive undifferentiated tumor). All anaplastic thyroid carcinomas are considered stage IV and are almost uniformly lethal, however most deaths are from papillary, follicular, and Hürthle cell carcinomas, which account for nearly 95% of thyroid carcinoma cases. The treatment of choice for differentiated thyroid carcinoma is surgery followed by radioiodine in selected patients and thyroxine therapy in most patients. There is no effective therapy for anaplastic thyroid carcinoma; most are unresectable, but EBRT may improve local control and provide palliation. Surgical resection is the primary treatment choice for medically unresponsive, symptomatic benign thyroid tumors and thyroid carcinomas. However, techniques for ablation of thyroid tumors (eg, RFA, microwave ablation) are being investigated.

SYSTEMATIC REVIEW

Benign Tumors: In 2014 Fuller reported on a systematic review and meta-analysis of studies on RFA for benign thyroid tumors.^[127] Included in the review were nine studies (five observational studies^[128-132], four randomized studies^[133-136]) 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, two of which were considered significant but did not require hospitalization.

Malignant Tumors: No systematic reviews of studies for malignant thyroid tumors were identified.

RANDOMIZED CONTROLLED TRIALS

No new RCTs were published since those included in the 2014 systematic review summarized above.

NONRANDOMIZED STUDIES

In 2016, Kim reported on a comparative review of 73 patients with recurrent thyroid cancer smaller than 2 cm who had been treated with RFA (n=27) or repeat surgery (n=46).^[137] RFA was performed in cases of patient refusal to undergo surgery or poor medical condition. Data were weighted to minimize potential confounders. The 3-year recurrence-free survival rates were similar for RFA (92.6%) and surgery (92.2%, p=0.681). Posttreatment hoarseness rate did not differ between the RFA (7.3%) and surgery (9.0%) groups. Posttreatment hypocalcemia occurred only in the surgery group (11.6%).

ADVERSE EVENTS

In 2017, Chung reported results of a systematic review and meta-analysis evaluating the safety of RFA for benign thyroid nodules and recurrent thyroid cancers.^[138] Twenty-four studies were included, totalling 2,421 participants and 2,786 thyroid nodules. Overall, 41 major complications and 48 minor complications (as defined by the Society of Interventional

Radiology) of RFA were reported, giving a pooled proportion of 2.38% for overall RFA complications [95% confidence interval (CI): 1.42%-3.34%] and 1.35% for major RFA complications (95% CI: 0.89%-1.81%). Subgroup analysis found major complication rates were significantly higher for malignant thyroid nodules than for benign. Major complications included voice change, nodule rupture, permanent hypothyroidism, and brachial plexus injury. Minor complications included pain, haematoma, vomiting, skin burns, and transient thyroiditis.

CHOLANGIOCARCINOMAS

BACKGROUND

Cholangiocarcinomas are tumors that originate in the bile duct epithelium; 90% are adenocarcinomas. Intrahepatic cholangiocarcinomas (ICC) are located within the hepatic parenchyma and are reviewed under Ablation of Primary and Metastatic Liver Tumors, Surgery, Policy No. 204 (see Cross References for a link to the policy). They may also be referred to as peripheral cholangiocarcinomas. Extrahepatic cholangiocarcinomas (ECC) are more common than intrahepatic cholangiocarcinoma and are located within the extrahepatic bile duct. Complete resection with negative margin is potential curative, though recurrence is common and most cases are unresectable due to advanced disease when diagnosed. For unresectable or metastatic cholangiocarcinomas at any location, the primary treatment may include chemotherapy, treatment within a clinical trial, or best supportive care. RFA and other locoregional therapies may be an option. Biliary drainage with biliary stenting may be warranted for unresectable or metastatic extrahepatic disease. Liver transplantation is potentially curative in carefully selected patients with lymph node negative, nondisseminated locally advanced hilar cholangiocarcinomas and otherwise normal biliary and hepatic function or underlying liver disease precluding surgery.

SYSTEMATIC REVIEWS AND RANDOMIZED CONTROLLED TRIALS

No systematic reviews or randomized controlled trials regarding radiofrequency ablation for the treatment of extrahepatic cholangiocarcinomas were identified.

NONRANDOMIZED STUDIES

The evidence for ECC consists of a single short-term case series.^[139] This study included 11 patients with hilar ECC. At 1-month follow-up after RFA, the reduction in tumor size was 30% in 6 tumors, 20% in 2 tumors, and size was unchanged in 3 tumors. At 6 months following RFA, the overall size reduction was 35%, with the largest reduction 60%. Overall survival ranged from 10-30 months.

UTERINE FIBROIDS (LEIOMYOMAS OR MYOMAS)

BACKGROUND

Uterine fibroids, also known as leiomyomas or myomas, are benign smooth muscle tumors of the uterus occurring in women during their reproductive years. They frequently occur in multiples, and the tumor location within the uterus is often used to describe the fibroids (intramural, submucosal, subserosal, or cervical myomas). Surgery, including hysterectomy and various myomectomy procedures, is considered the criterion standard treatment for symptom resolution. There has been long-standing research interest in developing minimally invasive alternatives for treating uterine fibroids, including procedures that retain the uterus

and allow for future childbearing. Various techniques to induce myolysis have also been studied including Nd:YAG lasers, bipolar electrodes, cryomyolysis, and radiofrequency ablation. With these techniques, an energy source is used to create areas of necrosis within uterine fibroids, reducing their volume and thus relieving symptoms.

SYSTEMATIC REVIEWS

No systematic reviews regarding radiofrequency ablation for the treatment of uterine fibroids were identified.

RANDOMIZED CONTROLLED TRIALS

In Germany in 2014, Brucker published a single-center manufacturer-sponsored randomized controlled trial (RCT) comparing radiofrequency volumetric thermal ablation (RFVTA) with the Acessa system to laparoscopic myomectomy.^[140] The trial included 51 premenopausal women at least 18 years old with symptomatic uterine fibroids less than 10 cm in any diameter and a uterine size of less than 17 weeks of gestation. Pregnancy and lactation were exclusion criteria. Prior to randomization, all women underwent laparoscopic ultrasound mapping. Data on 50 of the 51 women were analyzed. The primary study outcome, mean (SD) time to hospital discharge, was 10.0 (5.5) hours in the RFVTA group and 29.9 (14.2) hours in the myomectomy group. The criterion for noninferiority (no more than 10% longer hospital stay with RFVTA than laparoscopic myomectomy) was met at a significance level of $p < 0.001$. All patients in the myomectomy group were hospitalized overnight; although not explicitly stated, this appeared to be the standard procedure at the study hospital. In the Acessa group, there was 1 unplanned hospitalization due to unexplained vertigo and 4 hospitalizations as standard procedure because the patients also underwent adhesiolysis.

Secondary outcomes of the RCT were reported in a 2015 publication by Hahn^[141] (12-month outcomes) and a 2016 publication by Kramer^[142] (24-month outcomes). Analysis was per protocol and 43 (84%) of 51 randomized participants were available for both the 12- and 24-month analyses. Each publication reported on 12 symptoms: heavy menstrual bleeding, increased abdominal gait, dyspareunia, pelvic discomfort/pain, dysmenorrhea, urinary frequency, urinary retention, sleep disturbance, backache, localized pain, and “other symptoms” (not specified). At 12 months, no participants reported 4 of the symptoms (dyspareunia, urinary retention, sleep disturbance, uterine pain) and there were no statistically significant between-group differences in the frequency of any of the remaining 8 symptoms (at the $p < 0.05$ level). The most commonly reported symptom at 12 months (heavy menstrual bleeding) occurred in 7 (33%) of women in the RFVTA group and 2 (9%) of women in the laparoscopic myomectomy group ($p = 0.069$) after controlling for baseline bleeding. At 24 months, no participants reported urinary retention or “other” symptoms, and there were no statistically significant between-group differences in any of the 10 reported symptoms. The most commonly reported symptom at 24 months (dysmenorrhea) occurred in 8 (38%) in the RFVTA group and in 7 (32%) in the laparoscopic myomectomy group ($p = 0.67$). Patients were also assessed using several validated questionnaires (eg, the Uterine Fibroid Symptom and Quality of Life). There were no statistically significant between-group differences at 12 or 24 months on these validated questionnaires. In addition, the authors described pregnancy outcomes. Three patients in the RFVTA group conceived and all delivered a healthy neonate; the number of women who desired to become pregnant was not reported. Limitations of the 12- and 24-month analyses included lack of intention-to-treat analysis and failure to describe secondary study hypotheses and statistical analyses clearly. The RCT was relatively small in

size and thus may have been underpowered to detect clinically meaningful differences in secondary outcomes, so these results do not rule out potential differences between treatments.

NONRANDOMIZED STUDIES

A large retrospective case series was published by Yin in 2015.^[143] The study was conducted in China and used Chinese gynecologic radiofrequency ablation devices. It included 1216 consecutive patients treated at a single hospital over a 10-year period. All fibroids were less than 6 cm in size and mean diameter was 4.5 cm (range, 3.1-6.0 cm). Mean follow-up time was 36.5 months. Among the 476 premenopausal women, the mean reduction in myoma diameter was 2.7 cm at 6 months, 2.4 cm at 12 months, and 2.2 cm at 24 months. Among the 740 peri- or postmenopausal women, mean reduction was 3.3 cm at 6 months, 2.3 cm at 12 months, and 2.3 cm at 24 months. Myoma diameter was significantly lower at each of these time points posttreatment compared with pretreatment. In the premenopausal subgroup, the proportion of women with dysmenorrhea decreased from 43.7% at baseline to 7.6% at 12 months and to 6.7% at 24 months; rates were significantly lower after treatment.

In 2013, Chudnoff published a prospective industry-funded multicenter study.^[144] It included 135 premenopausal women at least 25 years old with symptomatic uterine fibroids, a uterine size of 14 weeks of gestation or less, and 6 or fewer treatable fibroids, with no single fibroid larger than 7 cm. In addition, women desired to preserve their uteri but not to have children in the future. RFVTA was conducted using the Acessa system. According to the study protocol, most fibroids less than 1 cm in diameter were not treated. The primary efficacy outcomes were change in the volume of menstrual bleeding and the surgical reintervention rate after 12 months. A total of 127 (94%) of 135 women completed the study. From baseline to 12 months, 53 (42%) of 127 women (95% confidence interval, 32% to 49%) experienced at least a 50% reduction in the volume of menstrual bleeding. Most women (104/127 [82%]) experienced a decrease in menstrual bleeding at 12 months. Only 1 woman underwent a surgical reintervention through 12 months (this woman had been lost to follow-up and was not included in the other efficacy analyses). Three-year outcomes were reported by Berman in 2014.^[145] A total of 104 (77%) of the 135 women who participated in the study were evaluable at 3 years. Fourteen underwent reintervention over the 3 years to treat uterine fibroid symptoms. Eleven women had hysterectomies, 2 had myomectomies, and 1 had uterine artery embolization. Bleeding outcomes were not reported at 3 years, but the authors stated that quality-of-life variables improved from baseline to 36 months and that most of the improvement in quality of life occurred within 3 months of the procedure.

MISCELLANEOUS TUMORS

BACKGROUND

The standard treatment of miscellaneous tumors depends on the type, location, and extent of the cancer. A large number of phase II or III clinical trials involving the use of RFA in the treatment of primary or metastatic cancers are underway.^[146]

PUBLISHED STUDIES

The current published evidence on RFA for other tumors is either absent or is limited to unreliable data from small case series and retrospective reviews. Evidence from these studies

is considered unreliable due to methodological limitations such as non-random allocation of treatment and a lack of appropriate comparison groups.^[122,128,129,147-160]

PRACTICE GUIDELINE SUMMARY

NATIONAL COMPREHENSIVE CANCER NETWORK (NCCN)

The NCCN guidelines for thyroid carcinoma (v.3.2018) state that for papillary carcinoma with locoregional recurrence surgery is preferred if resectable, and/or local therapies when available, including RFA.^[161] In symptomatic disease or progression of medullary carcinoma, consider palliative resection ablation (e.g., radiofrequency ablation, embolization, other regional therapy), or other regional treatment. (category 2A)

NCCN guidelines for colon cancer (v.4.2018) indicate that “ablative techniques can be considered [in patients whose primary colon tumor was resected for cure when metastatic lung tumors are] unresectable and amenable to complete ablation” (category 2A).^[162] The guidelines also 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 kidney cancer (v.2.2019) indicate RFA is an ablative option for the treatment of kidney cancer in select patients with clinical stage T1 lesions who are not candidates for surgery, though ablative techniques have shown higher local recurrence rates than surgery.^[163] RFA is also an option in select patients (e.g., elderly patients, others) with competing health risks.

AMERICAN COLLEGE OF RADIOLOGY

The 2014 American College of Radiology (ACR) Appropriateness Criteria® considers RFA to be an alternative to partial nephrectomy for small (<4 cm) RCC tumors.^[164]

The 2014 ACR Appropriateness Criteria on early-stage NSCLC that current evidence from a number of retrospective series involving varied patient populations reported a wide range of responses to RFA, ranging from 38% to 93%.^[165] Primary tumor relapse rate after RFA ranged from 8% to 43% and 2-year cancer-specific survival after RFA ranged from 57% to 93%, with 3-year OS of 15% to 46%. Predictors of complete response included smaller tumor size metastases, and ablation zone four times the tumor diameter. The document quoted the 2012 ACCP/STS guidelines^[166] summarized above.

AMERICAN COLLEGE OF CHEST PHYSICIANS

The American College of Chest Physicians (ACCP) guidelines on the treatment of stage I and II NSCLC 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.^[167]

The ACCP also joined with the Society of Thoracic Surgeons (STS) to develop consensus guidelines on the treatment of high-risk patients with stage I NSCLC.^[166] These consensus guidelines indicate RFA is an alternative treatment option in patients who are not surgical candidates due to severe medical comorbidity.

AMERICAN THYROID ASSOCIATION (ATA)

The 2012 ATA guidelines consider the evidence to be insufficient to allow conclusions as to the role of RFA, cryoablation, and embolization for the management of anaplastic thyroid cancer (ATC).^[168] Therefore, a definitive recommendation could not be made for these treatments. (Strength of Recommendation: Weak; Quality of Evidence: Insufficient)

SUMMARY

RENAL CELL CARCINOMA

Although there are currently no high-quality studies of radiofrequency ablation (RFA) of renal cell carcinoma (RCC), the overall body of published evidence suggests RFA may be beneficial in the short- to mid-term for small (4 cm or smaller), localized RCCs in patients who are not considered candidates for partial or complete surgical removal of the kidney. Therefore, RFA may be medically necessary for small RCCs in patients who are not surgical candidates or when preservation of kidney function is necessary, such as in patients with only one kidney.

Surgical excision is the preferred treatment for renal cell carcinoma (RCC) in patients who are considered to be healthy enough for surgery. There is insufficient evidence to determine whether radiofrequency ablation (RFA) is effective as surgical excision for treatment of RCC tumors. Therefore, RFA is considered investigational for treatment of RCC tumors for which surgical resection is an option.

BREAST TUMORS

There is insufficient evidence to determine the effectiveness of radiofrequency ablation for treatment of benign or malignant breast masses. Therefore, this treatment is considered investigational for the treatment of these tumors.

LUNG TUMORS

Surgical resection is the treatment of choice for primary non-small cell lung cancer (NSCLC) or metastatic tumors in the lung. For those patients who are unable to tolerate surgery, radiofrequency ablation (RFA) may be a treatment option in certain cases. While available studies are limited by study design, accumulating evidence suggests that RFA may be similar to surgery in survival rates, and rates of procedure-related complications and mortality. Therefore, in patients with NSCLC or metastatic tumors in the lung who are ineligible for surgical treatment, RFA may be medically necessary when the policy criteria are met. RFA is considered investigational when the policy criteria are not met.

OSTEOID OSTEOMAS

Although the published evidence is limited to studies of lower methodological quality, radiofrequency ablation (RFA) of osteomas has become a standard of care based on expert opinion that the potential benefits of RFA outweigh risks in patients with osteoid tumors who have failed nonsurgical treatments. Therefore, RFA may be medically necessary for select patients when policy criteria are met.

The current preferred treatment of osteoid osteomas is non-surgical medical treatment. There is insufficient evidence to determine the effectiveness of radiofrequency ablation

(RFA) for initial (first-line) treatment of osteoid tumors. RFA is, therefore, considered investigational as initial treatment of these tumors in patients who have not undergone standard medical management.

ANGIOMYOLIPOMAS

The current published evidence on radiofrequency ablation (RFA) of angiomyolipomas (AMLs) is limited to studies of lower methodological quality. However, because these tumors are rare, it is unlikely that evidence from large comparative studies will become available. Given the potential for life-threatening hemorrhage from large AMLs (4 cm or larger), and the consistent reports that the potential benefits of treatment outweigh any risks, RFA may be medical necessary to treat symptomatic or large asymptomatic AMLs. Treatment of asymptomatic AMLs smaller than 4 cm is considered investigational.

PALLIATION OF PAIN FOR BONE METASTASES

The current evidence for radiofrequency ablation (RFA) for treatment of painful metastatic tumors in the bone is limited to studies of lower methodological quality; however, these studies have consistently reported significant improvement in pain following RFA in patients who have failed or are poor candidates for standard treatments. In light of this evidence, the unlikelihood of randomized controlled trials in these patients, and the lack of treatment options, the potential benefits of RFA appear to outweigh risks. Therefore, RFA may be medically necessary in patients with painful metastatic bone lesions who have failed or are poor candidates for standard treatments.

Because of the lack of data on the effectiveness of radiofrequency ablation (RFA) for initial (first-line) treatment of painful bony metastases, this indication is considered investigational.

HEAD AND NECK CANCERS

There is insufficient evidence to determine whether radiofrequency ablation (RFA) is effective for treatment of tumors of the head and neck. Therefore, RFA is considered investigational for the treatment of head and neck cancers.

THYROID TUMORS

While radiofrequency ablation (RFA) has been shown to reduce the size of thyroid tumors and improve clinical symptoms, complications can be common. The available evidence is insufficient to determine whether any beneficial effects of RFA outweigh the risks. Therefore, RFA for the treatment of benign or malignant thyroid tumors is considered investigational.

UTERINE FIBROIDS

There is not enough research to show that radiofrequency ablation (RFA) improves health outcomes for people with uterine fibroids. Additionally, no clinical guidelines based on evidence recommend this treatment option. Therefore, RFA is considered investigational for treating uterine fibroids.

MISCELLANEOUS TUMORS

There is insufficient evidence to determine whether radiofrequency ablation (RFA) is effective for treatment of other tumors. Therefore, RFA is considered investigational for all other tumors.

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169. BlueCross BlueShield Association Medical Policy Reference Manual "Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors." Policy No. 7.01.95

170. BlueCross BlueShield Association Medical Policy Reference Manual "Laparoscopic and Percutaneous Techniques for the Myolysis of Uterine Fibroids." Policy No. 4.01.19

CODES

Codes	Number	Description
CPT	20982	Ablation therapy for reduction or eradication of 1 or more bone tumors (eg, metastasis) including adjacent soft tissue when involved by tumor extension, percutaneous, including imaging guidance when performed; radiofrequency
	31641	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with destruction of tumor or relief of stenosis by any method other than excision (eg, laser therapy, cryotherapy)
	32998	Ablation therapy for reduction or eradication of 1 or more pulmonary tumor(s) including pleura or chest wall when involved by tumor extension, percutaneous, including imaging guidance when performed, unilateral; radiofrequency
	50542	Laparoscopy, surgical; ablation of renal mass lesion(s), including intraoperative ultrasound guidance and monitoring, when performed
	50592	Ablation, one or more renal tumor(s), percutaneous, unilateral, radiofrequency
	58674	Laparoscopy, surgical, ablation of uterine fibroid(s) including intraoperative ultrasound guidance and monitoring, radiofrequency
	0404T	Transcervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency
HCPCS	None	

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