BlueCross BlueShield of Alabama

For dates of service February 26, 2018 and after for Lung tumors see L36954 -Palmetto

Name of Blue Advantage Policy*:*

Radiofrequency Ablation of Solid Tumors Excluding Liver Tumors

Policy #: 119 | Latest Review Date: September 2020
Category: Surgery | Policy Grade: B

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*

   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

<u>Effective for dates of service on or after February 26, 2018:</u>

Blue Advantage will treat r**adiofrequency ablation** as a **covered benefit** for the treatment of patients with the following conditions:

- Renal cell carcinoma
    - In order to preserve kidney function in patients with significantly impaired renal function (i.e., the patient has one kidney or renal insufficiency defined by a glomerular filtration rate [GFR] of less than 60mL/min/m^2) when the standard surgical approach (i.e., resection of renal tissue) is likely to substantially worsen existing kidney function

    OR
    - The patient is not considered a surgical candidate
- Osteoid osteomas that cannot be managed successfully with medical treatment
- Osteolytic bone metastases that have failed or are poor candidates for standard treatments such as radiation or opioids
- Isolated peripheral non-small cell lung cancer lesion ≤ 3cm*,

    AND
    - 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 ≤ 3cm*,

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

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

Blue Advantage will treat **radiofrequency ablation** as a **non-covered benefit** and as **investigational** as a technique for ablation of:

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

- Other tumors outside the liver, including but not limited to the head and neck, thyroid, adrenal gland, ovary, and pelvis/abdominal metastases of unspecified origin.

Please refer to Blue Advantage Policy #178 for coverage information on ultrasound ablation of the bone
Please refer to Blue Advantage Policy #429 for coverage information on cryosurgical ablation of renal, bone, and pulmonary tumors
Please refer to Blue Advantage *NCD for Cryosurgery of Prostate (230.9)*
Please refer to Blue Advantage Policy #070 for coverage information on locoregional therapies for liver tumors
Please refer to Policy# 596 for coverage information on focal treatments for prostate cancer.

Effective for dates of service April 27, 2015 through February 25, 2018:
Blue Advantage will treat **radiofrequency ablation** as a **covered benefit** for the treatment of patients with the following conditions:

- Renal cell carcinoma
  - In order to preserve kidney function in patients with significantly impaired renal function (i.e., the patient has one kidney or renal insufficiency defined by a glomerular filtration rate [GFR] of less than 60mL/min/m^2) when the standard surgical approach (i.e., resection of renal tissue) is likely to substantially worsen existing kidney function

  OR
  - The patient is not considered a surgical candidate
- Osteoid osteomas that cannot be managed successfully with medical treatment
- Osteolytic bone metastases that have failed or are poor candidates for standard treatments such as radiation or opioids
- Isolated peripheral non-small cell lung cancer lesion ≤ 3cm*,

  And
  - 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 ≤ 3cm*,

  And
  - 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

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

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

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- Renal cell cancer not meeting the criteria above
- Osteoid osteomas that can be managed with medical treatment
- Painful bony metastases as initial treatment
- Lung cancer not meeting the above criteria
- Breast tumors
- Other tumors outside the liver, including but not limited to the head and neck, thyroid, adrenal gland, ovary, and pelvis/abdominal metastases of unspecified origin

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Please refer to Blue Advantage Policy #070 for coverage information on locoregional therapies for liver tumors
Please refer to Policy# 596 for coverage information on focal treatments for prostate cancer.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

In radiofrequency ablation (RFA), a probe is inserted into the center of a tumor, then non-insulated, prong-shaped electrodes are projected into the tumor. Next, heat is generated locally by a high-frequency, alternating current that flows from the electrodes. The localized 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. RFA may be performed percutaneously, laparoscopically, or as an open procedure.

Renal Cell Carcinoma (RCC)

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).

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

Osteoid Osteomas
Osteomas are the most common benign bone tumor, comprising 10–20% of benign and 2–3% of all bone tumors. They are typically seen in children and young adults, with most diagnosed in patients between five to 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 1.5cm, 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 three to seven years.

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

Primary Pulmonary Tumors and Metastases

Surgery is the current treatment of choice in patients with Stage I primary non-small cell lung carcinoma (NSCLC). (Stage I includes Ia: T1N0M0 and Ib: T2N0M0). Only approximately 20% of patients present with Stage I 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 I NSCLC have been reported between 20% and 30%, with most occurring at distant sites; locoregional recurrences occur in approximately 12%. Large differences in survival outcome are observed after surgery in Stage I patients, with five-year overall survival (OS) rates, ranging from 77% for small T1 tumors to 35% for large T2 tumors. Untreated, Stage I NSCLC has a five-year OS rate of 6–14%.

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

Stereotactic whole body radiation therapy (SBRT) 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 three-year local control rates of Stage I NSCLC with SBRT have ranged from 80 to 95%. SBRT has been investigated in patients unfit to undergo surgery, with survival rates similar to surgical outcomes.

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

Breast Tumors

The treatment of small breast cancers has evolved from total mastectomy toward 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.

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, microwave ablation) are being investigated.

Miscellaneous Tumors
Radiofrequency ablation has been investigated for use in individuals with different lesions in different anatomic sites. This includes, but is not limited to, breast and head and neck.

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.

Radiofrequency Ablation
Radiofrequency ablation (RFA) was initially developed to treat inoperable tumors of the liver. 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 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 (eg, intestinal damage during RFA of kidney), structural damage along the probe track (eg, pneumothorax as a consequence of procedures on the lung), and secondary tumors (if cells seed during probe removal).

KEY POINTS:
The most recent literature search was performed through July 27, 2020.

Summary of Evidence:
Renal cell carcinoma
For individuals who have localized RCC who receive RFA, the evidence includes an RCT, numerous observational studies, and systematic reviews of these studies. The relevant outcomes are overall survival (OS), change in disease status, QOL, and treatment-related morbidity. A meta-analysis that included only an RCT and cohort studies found that RFA was as effective as nephrectomy for small renal tumors, with a reduction in complications. Another recent meta-analysis found that partial nephrectomy was superior to ablative techniques (the study included RFA, but also cryoablation and microwave ablation) in overall mortality and local recurrence but not in cancer-specific mortality. It also found fewer complications and improved renal function

with ablation.Although inconsistent, the evidence does suggest that for small renal tumors, RFA may result in a similar rate of disease progression with a lower complication rate than nephrectomy. The evidence is sufficient to determine the effects of the technology on health outcomes.

Osteolytic Bone Metastases

For individuals who have painful osteolytic bone metastases who have failed or are poor candidates for standard treatments who receive RFA, the evidence includes case series. The relevant outcomes are symptoms, change in disease status, quality of life (QOL), and medication use. Case series show clinically significant pain relief and reduction in opioid use following treatment of osteolytic pain metastases. The population is comprised of patients with limited or no treatment options, for whom short-term pain relief is an appropriate outcome. Therefore, the evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Osteoid osteomas

For individuals who have painful osteoid osteomas who receive RFA, the evidence includes numerous observational studies and systematic reviews of these studies. The relevant outcomes are symptoms, change in disease status, QOL, medication use, and treatment-related morbidity. In a systematic review of thermal ablation techniques, clinical success (pain free) was achieved in 94% to 98% of patients. Most patients (89% to 96%) remain pain-free when assessed at longer-term follow-up. Another systematic review reported similar success rates noting an average 8.3% failure rate among patients receiving computed tomography-guided RFA. Although no randomized trials of RFA for osteoid osteomas have been performed, the uncontrolled studies have demonstrated RFA can provide adequate symptomatic relief with minimal complications, for whom short-term symptom relief and avoidance of invasive procedures are appropriate clinical outcomes. Therefore, the evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Inoperable Primary Pulmonary Tumors and Metastatic to Lung

For individuals who have inoperable primary pulmonary tumors or non-pulmonary tumors metastatic to the lung who receive RFA, the evidence includes prospective observational studies and systematic reviews of these studies. The relevant outcomes areOS, change in disease status, QOL, and treatment-related morbidity. A multicenter study found that, for tumors less than 3.5 cm, RFA can lead to a complete response in as many as 88% of patients for at least 1 year. Two-year survival has been reported to range from 41% to 75% in case series, with 5-year survival rates of 20% to 27%. In general, the evidence shows RFA results in adequate survival and tumor control in patients who are not surgical candidates, with low morbidity rates. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

Breast Tumors

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

Benign Thyroid Tumors

For individuals who have benign thyroid tumors who receive RFA, the evidence includes RCTs, prospective studies, case series, and systematic reviews of these studies. Relevant outcomes are symptoms, change in disease status, QOL, medication use, and treatment related morbidity. Systematic reviews have demonstrated that RFA results in a significant reduction in thyroid nodule size with a 2020 review showing that these changes remain durable through at least 36 months. Complication rates are generally low, but include voice changes. The data are limited by significant heterogeneity in meta-analyses, a lack of generalizability to populations outside Republic of Korea and Italy, and a lack of comparators more relevant to practice in the United States. Further studies comparing RFA to percutaneous ethanol injection or surgery would be more informative in determining the potential utility of RFA in patients with symptomatic or large benign thyroid tumors as these are the recommended treatment options per the American Thyroid Association. The evidence is insufficient to determine the effects of the technology on health outcomes.

Miscellaneous Tumors

For individuals who have miscellaneous tumors (e.g. head and neck and pancreas) who receive RFA, the evidence includes a few case series, prospective observational studies, and retrospective comparative studies. The relevant outcomes areOS, change in disease status, QOL, and treatment-related morbidity. There is a limited evidence base for each of these tumor types. These studies do not permit conclusions on the health benefits of RFA. The evidence is insufficient to determine the impact of technology on health outcomes.

Practice Guidelines and Position Statements:

American College of Chest Physicians

The American College of Chest Physicians (2013) guidelines on the treatment of stage I and II non-small-cell lung cancer (NSCLC) have indicated RFA has been used effectively in clinical stage I NSCLC.Therefore, in medically inoperable patients, peripheral NSCLC tumors less than 3 cm may be treated with RFA. The College also collaborated with the Society of Thoracic Surgeons to develop consensus guidelines on the treatment of high-risk patients with stage I NSCLC.These 2012 consensus guidelines indicated RFA is an alternative treatment optionfor patients who are not surgical candidates due to severe medical comorbidity.

American Urological Association

The American Urological Association (2017) guideline on renal masses and localized renal cancer affirms that partial nephrectomy should be prioritized for management of cT1a renal masses when intervention is indicated. Thermal ablation should be considered "as an alternate approach for the management of cT1a renal masses <3 cm in size."

American Thyroid Association
The American Thyroid Association (2015) guideline on management of thyroid nodules and differentiated thyroid cancer. Patients with a benign cytology diagnosis or those very unlikely to be malignant (eg, purely cystic nodule) should undergo surveillance with the frequency determined by the level of suspicion for a missed malignancy. Medical or surgical intervention is considered if the nodules are large (>4 cm), causing compressive or structural symptoms, or if there is clinical concern. Recurrent cystic thyroid nodules with benign cytology should be considered for surgical removal or percutaneous ethanol injection. For differentiated thyroid cancer, "localized treatments with thermal (radiofrequency or cryo-) ablation, ethanol ablation, or chemoembolization may be beneficial in patients with a single or a few metastases and in those with metastases at high risk of local complications."

National Comprehensive Cancer Network
NCCN guidelines for the treatment of non-small cell lung cancer(v.6.2020) state: “For medically operable disease, resection is the preferred local treatment modality (other modalities include SABR, thermal ablation such as radiofrequency ablation and cryotherapy).”

The NCCN guidelines for thyroid carcinoma (v.2.2020) indicate that local therapies such as radiofrequency ablation may be considered for locoregional recurrence of thyroid carcinoma-papillary carcinoma in select patients with limited burden nodal disease. Additionally, local therapies, including RFA, can be considered in those with metastatic disease.

The NCCN guidelines (v.1.2021) for renal cancer indicate that “[t]hermal ablation (eg, cryosurgery, radiofrequency ablation) is an option for the management of patients with clinical stage T1 renal lesions. Thermal ablation is an option for masses 3 cm is associated with higher rates of local recurrence/persistence and complications.”

The NCCN colon cancer guidelines (v.4.2020), which are currently under discussion, state that “for the local treatment of resectable metastatic disease, patients with liver or lung oligometastases can be considered for tumor ablation therapy….Evidence on the use of RFA as a reasonable treatment option for non-surgical candidates and those with recurrent disease after hepatectomy with small liver metastases that can be treated with clear margins is growing.”

The NCCN guidelines for head and neck cancers (v.2.2020) and pancreatic adenocarcinoma (v.1.2020) do not mention RFA.

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

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

The NICE guidance on RFA for primary and secondary lung cancers issued in 2010 states, "[C]urrent evidence on the efficacy of percutaneous radiofrequency ablation (RFA) for primary or secondary lung cancers is adequate in terms of tumor control." The NICE 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." The guidance warns of complications such as pneumothorax, which can result in serious consequences among lung cancer patients.

The NICE guidance issued in 2016 stated "Current evidence on the safety and efficacy of ultrasound-guided percutaneous radiofrequency ablation for benign thyroid nodules is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit."

U.S. Preventive Services Task Force Recommendations
Not applicable.

KEY WORDS:

Renal cell carcinoma, RCC, radiofrequency ablation, RF, RF ablation, RFA, percutaneous radiofrequency ablation, pulmonary tumor, lung cancer, breast cancer, head and neck, cancer, adrenal, ovary, pelvic and/or abdominal tumor, osteoid tumor, bone metastases, palliation of pain, thyroid cancer, osteoid osteoma, metastatic bone cancer

APPROVED BY GOVERNING BODIES:

The U.S. Food and Drug Administration (FDA) issued a statement in September 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. Under this general indication, RFA can be used to ablate tumors, including lung tumors. 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.

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT codes

19499	Unlisted Procedure, Breast
20982	Ablation therapy for reduction or eradication of 1 or more bone tumors (e.g., metastasis) including adjacent soft tissue when involved by tumor extension, percutaneous, including imaging guidance when performed; radiofrequency
32998	Ablation therapy for reduction or eradication of one or more pulmonary tumor(s) including pleura or chest wall when involved by tumor extension, percutaneous, including imaging guidance when performed, unilateral; radiofrequency
50542	Laparoscopy, surgical; ablation of renal mass lesion(s)
50592	Ablation, one or more renal tumor(s), percutaneous, unilateral, radiofrequency
76940	Ultrasound guidance for, and monitoring of, parenchymal tissue ablation

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POLICY HISTORY:

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