Corporate Medical Policy

Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors

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Description of Procedure or Service

In radiofrequency ablation (RFA), a probe is inserted into the center of a tumor. The non-insulated electrodes, which are shaped like prongs, are projected into the tumor. 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 or laparoscopically with ultrasound or computed tomography guidance, or as an open procedure.

RFA 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).

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).

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.

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

opioid medications. RFA has been investigated as another alternative for palliating pain from bone metastases.

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

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

Renal cell carcinoma (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).

Breast tumors. The treatment of small breast cancers has evolved 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.

Pulmonary tumors. Surgery is the current treatment of choice in patients with stage 1 primary non-small cell lung carcinoma (NSCLC). (Stage 1 includes 1a: T1N0M0 and 1b: T2N0M0). Only

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

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

Stereotactic body radiotherapy (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 3-year local control rates of stage 1 NSCLC with SBRT have ranged from 80–95%. 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.

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

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

Regulatory Issues

The U.S. Food and Drug Administration (FDA) issued a statement September 24, 2008 concerning the regulatory status of radiofrequency ablation. The FDA has cleared RF ablation devices for the general indication of soft tissue cutting, coagulation, and ablation by thermal coagulation necrosis. Under this general indication, RF ablation can be used as a tool to ablate tumors, including lung tumors. 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.

Related Policies:
Radiosurgery, Stereotactic Approach
Cryosurgical Ablation of Miscellaneous Solid Tumors Other Than Liver, Prostate, or Dermatologic Tumors
Microwave Tumor Ablation

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

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Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors

Policy

BCBSNC will provide coverage for radiofrequency ablation of miscellaneous tumors when it is determined to be medically necessary because the medical criteria and guidelines noted below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Radiofrequency Ablation of Miscellaneous Solid Tumors is covered

1. Palliation of Pain from Bone Metastases.

Radiofrequency ablation may be considered medically necessary to palliate pain in patients with osteolytic bone metastases who have failed or are poor candidates for standard treatments such as radiation or opioids.

2. Osteoid Tumors

Radiofrequency ablation may be considered medically necessary to treat osteoid osteomas that cannot be managed successfully with medical treatment.

3. Renal Tumors

Radiofrequency ablation may be considered medically necessary to treat localized renal cell carcinoma that is no more than 4 cm in size when either of the following criteria are met:

a. In order to preserve kidney function in patients with significantly impaired renal function (i.e., the patient has one kidney or renal insufficiency defined by a glomerular filtration rate [GFR] of less than 60 mL/min/m2) when the standard surgical approach (i.e., resection of renal tissue) is likely to substantially worsen existing kidney function; OR
b. The patient is not considered a surgical candidate.

4. Primary Pulmonary Tumors

Radiofrequency ablation may be considered medically necessary to treat an isolated peripheral non-small cell lung cancer lesion that is no more than 3 cm in size when the following criteria are met:

a. Surgical resection or radiation treatment with curative intent is considered appropriate based on stage of disease, however, medical co-morbidity renders the individual unfit for those interventions; AND
b. Tumor is located at least 1 cm from the trachea, main bronchi, esophagus, aorta, aortic arch branches, pulmonary artery and the heart.

5. Metastatic Pulmonary Tumors

Radiofrequency ablation may be considered medically necessary to treat malignant non-pulmonary tumor(s) metastatic to the lung that are no more than 3 cm in size when the following criteria are met:

a. 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
b. There is no evidence of extrapulmonary metastases; AND

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

(See the Policy Guidelines for additional criteria)

When Radiofrequency Ablation of Miscellaneous Solid Tumors is not covered

Radiofrequency ablation is considered **investigational** as a technique for the following:

- ablation of tumors of the breast,
- lung cancer not meeting the criteria above,
- renal cell cancer not meeting the criteria above, and
- all other tumors outside the liver including, but not limited to, the head and neck, thyroid, pancreas, adrenal gland, ovary, and pelvic/abdominal metastases of unspecified origin.

Radiofrequency ablation is considered **investigational** as a technique for the treatment of osteoid osteomas that can be managed with medical treatment.

Radiofrequency ablation is considered **investigational** as a technique for initial treatment of painful bony metastases.

Policy Guidelines

Palliation of Pain from 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. Relevant outcomes are symptoms, change in disease status, quality of life, medication use, and treatment-related morbidity. Case series have shown clinically significant pain relief and reduction in opioid use following treatment of painful osteolytic metastases. The patient population is comprised of patients with limited or no treatment options, for whom short-term pain relief is an appropriate clinical outcome. Therefore, the evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Because data were 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.

Osteoid Osteomas

For individuals who have painful osteoid osteomas who receive RFA, the evidence includes numerous observational studies and a systematic review of these studies. Relevant outcomes are symptoms, change in disease status, quality of life, 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%-96%) remained pain-free when assessed at longer term follow-up. Although no randomized trials of RFA for osteoid osteomas have been performed, the uncontrolled studies have demonstrated RFA can provide adequate symptomatic relief with minimal complications in individuals with limited or no other treatment options, for whom short-term symptom relief and avoidance of invasive procedures are appropriate clinical outcomes. Therefore, the evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Localized Renal Cell Carcinoma

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For individuals who have localized renal cell carcinoma that is no more than 4 cm in size who receive RFA, the evidence includes one randomized controlled trial (RCT), a large number of observational studies, and systematic reviews of these studies. Relevant outcomes are overall survival, change in disease status, quality of life, and treatment-related morbidity. A recent 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, which included case series of stage 1 (≤7 cm across) renal tumors, found that the rate of local progression was greater with RFA than with nephrectomy. The differing results in these meta-analyses may be due to differences in tumor size in selected studies as well as potential selection bias when evaluating case series. 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. However, comparative trials are needed to determine with greater certainty the effects of these treatments in the same patient population. The evidence is insufficient to determine the effects of the technology on health outcomes.

Clinical input supported RFA for localized renal cell carcinoma that is no more than 4 cm in size when preservation of kidney function is necessary and a standard surgical approach is likely to substantially worsen kidney function or when the patient is not considered a surgical candidate. Thus, absent other treatment options, RFA for small renal cell tumors may be considered medically necessary.

Inoperable Pulmonary Tumors and Nonnpulmonary Metastases

For individuals who have inoperable primary pulmonary tumors or nonpulmonary tumors metastatic to the lung who receive RFA, the evidence includes prospective observational studies and systematic reviews of these studies. Relevant outcomes are overall survival, change in disease status, quality of life, 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 that the technology results in a meaningful improvement in the net health outcome.

Metastatic Pulmonary Tumors

The following are additional criteria that have been developed by clinical judgment/consensus and existing guidelines for the use of RFA in metastatic tumors to the lung and include:

- 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.

Breast Tumors

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

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, quality of life, medication use, and treatment-related morbidity. A systematic review that included four RCTs and five observational studies found significant reductions in nodule size and withdrawal from methimazole following treatment with RFA when compared with a variety of local treatments. Reports of complications have varied. The most frequent major complication from a large multicenter series of specialty centers was voice change. The evidence is insufficient to determine the effects of the technology on health outcomes.

Miscellaneous Solid Tumors
For individuals who have miscellaneous tumors (eg, head and neck, thyroid cancer, pancreas) who receive RFA, the evidence includes a small number of case series and retrospective comparative studies. Relevant outcomes are overall survival, change in disease status, quality of life, and treatment-related morbidity. There is a limited evidence base for each tumor type. Reporting on outcomes or comparisons with other treatments is limited. These studies do not permit conclusions on the health benefits of RFA. The evidence is insufficient to determine the impact of the technology on health outcomes.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 20982, 32998, 50542, 50592, 76940

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

Former EBG or Policies:
Radiofrequency Ablation of Osteoid Osteomas and Bone Metastases
Radiofrequency Ablation of Pulmonary Tumors
Cryosurgical or Radiofrequency Ablation of Renal Cell Cancer

Radiofrequency Ablation of Miscellaneous Tumors
BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.95, 10/4/2011

Medical Director - 12/2011

Specialty Matched Consultant Advisory Panel meeting- 5/2012

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.95, 10/11/12

Specialty Matched Consultant Advisory Panel 5/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.95, 10/10/13

Specialty Matched Consultant Advisory Panel 5/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.95, 10/09/14

Specialty Matched Consultant Advisory Panel 5/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.95, 9/10/15

Specialty Matched Consultant Advisory Panel 5/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.95, 9/8/16

Specialty Matched Consultant Advisory Panel 5/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.95, 9/14/17

Specialty Matched Consultant Advisory Panel 5/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.95, 9/13/18

Specialty Matched Consultant Advisory Panel 6/2019

Policy Implementation/Update Information

12/20/11 The following policies/EBGs were combined for this policy: Radiofrequency Ablation of Osteoid Osteomas and Bone Metastases, Radiofrequency Ablation of Pulmonary Tumors, and Cryosurgical or Radiofrequency Ablation of Renal Cell Cancer Policy statements changed to indicate medically necessary options for primary and metastatic pulmonary tumors. "Radiofrequency ablation is considered **investigational** as a technique for ablation of tumors of the breast, lung cancer not meeting the criteria above, renal cell cancer not meeting the criteria above, and all other tumors outside the liver including, but not limited to, the head and neck, adrenal gland, ovary, and pelvic/abdominal metastases of unspecified origin and for the treatment of osteoid osteomas that can be managed with medical treatment and for initial treatment of painful bony metastases." Medical Director review 12/2/2011. References added.(btw)

5/29/12 Specialty Matched Consultant Advisory Panel review 5/16/12. No change to policy statement. (sk)

11/27/12 Reference added. Information on thyroid tumors added to Description section. Thyroid tumors added to non covered indications. Policy Guidelines updated. Medical Director review. Notification given 11/27/12. Policy effective 2/26/13. (sk)

5/28/13 Specialty Matched Consultant Advisory Panel review 5/15/13. No change to policy statement. (sk)

11/26/13 Reference added. No change to Policy statement. (sk)

6/10/14 Specialty Matched Consultant Advisory Panel review 5/27/14. No change to policy statement. (sk)

12/30/14 Reference added. Codes 47380 and 47382 added to Billing/Coding section. No change to Policy statement. (sk)

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7/1/15 Specialty Matched Consultant Advisory Panel review 5/27/15. Removed related policy Radiofrequency Ablation Primary or Metastatic Liver Tumors as that policy has been archived. (sk)

10/30/15 Reference added. Policy guidelines updated. No change to Policy statement. (sk)

7/1/16 Specialty Matched Consultant Advisory Panel review 5/25/16. (sk)

11/22/16 Reference added. Policy Guidelines updated. (sk)

6/30/17 Specialty Matched Consultant Advisory Panel review 5/31/17. (sk)

10/27/17 Reference added. Microwave Tumor Ablation added to Related Policies list. Codes 47380 and 47382 removed from Billing section as they pertain to liver tumors. (sk)

6/29/18 Specialty Matched Consultant Advisory Panel review 5/23/18. (sk)

11/30/18 Reference added. (sk)

7/16/19 Specialty Matched Consultant Advisory Panel review 6/28/2019. (sk)

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