MASSACHUSETTS

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Medical Policy

Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors

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Policy Number: 259

BCBSA Reference Number: 7.01.95
NCD/LCD: NA

Related Policies

- Cryosurgical Ablation of Miscellaneous Solid Tumors Other Than Liver, Prostate or Dermatologic Tumors, #260
- Radiofrequency Ablation of Primary or Metastatic Liver Tumors, #286
- Stereotactic Radiosurgery and Stereotactic Body Radiation Therapy, #277

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue[SM] and Medicare PPO Blue[SM] Members

Radiofrequency ablation may be **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.

Radiofrequency ablation may be **MEDICALLY NECESSARY** to treat osteoid osteomas that cannot be managed successfully with medical treatment.

Radiofrequency ablation may be **MEDICALLY NECESSARY** to treat localized renal cell carcinoma that is no more than 4 cm in size when either of the following criteria is met:

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

Radiofrequency ablation may be **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:

- 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.

Radiofrequency ablation may be **MEDICALLY NECESSARY** to treat malignant non-pulmonary tumor(s) metastatic to the lung when there are no more than 3 tumors per lung and twelve months have elapsed before a repeat ablation is considered:

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

The tumors:

- Should no more than 3 cm in size AND
- Amenable to complete ablation.

Radiofrequency ablation is considered **INVESTIGATIONAL** in the following conditions:

- 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, thyroid, 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.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is **not required**.
Commercial PPO and Indemnity	Prior authorization is **not required**.
Medicare HMO Blue℠	Prior authorization is **not required**.
Medicare PPO Blue℠	Prior authorization is **not required**.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

CPT codes:	

	Code Description
20982	Ablation, bone tumor(s) (e.g. osteoid osteoma, metastasis) radiofrequency, percutaneous, including computed tomographic guidance

The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT codes above if medical necessity criteria are met:

ICD-10 Diagnosis Codes

ICD-10-CM Diagnosis codes:	Code Description
C79.51	Secondary malignant neoplasm of bone
C79.52	Secondary malignant neoplasm of bone marrow
D16.00	Benign neoplasm of scapula and long bones of unspecified upper limb
D16.01	Benign neoplasm of scapula and long bones of right upper limb
D16.02	Benign neoplasm of scapula and long bones of left upper limb
D16.10	Benign neoplasm of short bones of unspecified upper limb
D16.11	Benign neoplasm of short bones of right upper limb
D16.12	Benign neoplasm of short bones of left upper limb
D16.20	Benign neoplasm of long bones of unspecified lower limb
D16.21	Benign neoplasm of long bones of right lower limb
D16.22	Benign neoplasm of long bones of left lower limb
D16.30	Benign neoplasm of short bones of unspecified lower limb
D16.31	Benign neoplasm of short bones of right lower limb
D16.32	Benign neoplasm of short bones of left lower limb
D16.4	Benign neoplasm of bones of skull and face
D16.5	Benign neoplasm of lower jaw bone
D16.6	Benign neoplasm of vertebral column
D16.7	Benign neoplasm of ribs, sternum and clavicle
D16.8	Benign neoplasm of pelvic bones, sacrum and coccyx
D16.9	Benign neoplasm of bone and articular cartilage, unspecified

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

CPT codes:	Code Description
50592	Ablation, 1 or more renal tumor(s), percutaneous, unilateral, radiofrequency

The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT codes above if medical necessity criteria are met:

ICD-10 Diagnosis Codes

ICD-10-CM Diagnosis codes:	Code Description
C64.1	Malignant neoplasm of right kidney, except renal pelvis
C64.2	Malignant neoplasm of left kidney, except renal pelvis
C64.9	Malignant neoplasm of unspecified kidney, except renal pelvis

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

CPT codes:	Code Description
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

The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT codes above if medical necessity criteria are met:

ICD-10 Diagnosis Codes

ICD-10-CM Diagnosis codes:	Code Description
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
C38.4	Malignant neoplasm of pleura
C78.00	Secondary malignant neoplasm of unspecified lung
C78.01	Secondary malignant neoplasm of right lung
C78.02	Secondary malignant neoplasm of left lung
C78.1	Secondary malignant neoplasm of mediastinum
C78.2	Secondary malignant neoplasm of pleura

Description

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.

Treatment
External-beam radiotherapy often is the initial palliative therapy for osteolytic bone metastases. However, pain from bone metastases is refractory to radiotherapy 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 (eg, strontium 89), and bisphosphonates. Less often, surgery or chemotherapy may be used for palliation, and intractable pain may require opioid medications. Radiofrequency ablation (RFA) has been investigated as an alternative for palliation of bone metastases.

OSTEOID OSTEOMAS
Osteomas are the most common benign bone tumor, comprising 10% to 20% of benign and 2% to 3% of all bone tumors. They are typically seen in children and young adults, with most diagnosed in patients between 5 and 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. The natural history of the osteoid osteoma varies based on location, and although they rarely exceed 1.5 cm in diameter, 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 to 7 years.

Treatment
Treatment options include medical management with NSAIDs, surgical excision (wide/en bloc excision or curetting), or the use of computed tomography– 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. However, a substantial incision may be necessary, with the removal of a considerable amount of bone (especially in the neck of the femur). This increases the need for bone grafting plus 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 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; further, patients may immediately walk on the treated extremity and return to daily activities when 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.

LOCALIZED RENAL CELL CARCINOMA
Radical nephrectomy remains the principal treatment of renal cell carcinoma; 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 (eg, 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 (eg, von Hippel-Lindau disease).

PRIMARY PULMONARY AND NONPULMONARY TUMORS
Surgery is the current treatment of choice in patients with stage I primary non-small-cell lung cancer (NSCLC; stage I includes Ia [T1N0M0] and 1b [T2N0M0]). 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 computed tomography scans for other indications. Postsurgical recurrence rates of stage I NSCLC have been reported as between 20% and 30%, with most occurring at distant sites; locoregional recurrences occur in approximately 12%. Large differences in survival outcome are observed after surgery in stage I patients, with 5-year overall survival rates ranging

from 77% for small T1 tumors to 35% for large T2 tumors. Untreated, stage I NSCLC has a 5-year overall survival rate range from 6% to 14%.

Patients with early-stage NSCLC who are not surgical candidates may be candidates for radiotherapy with curative intent. In 2 large retrospective radiotherapy series, patients with inoperable disease treated with definitive radiotherapy 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 has gained more widespread use as a treatment option because it is a high-precision mode of therapy that delivers very high doses of radiation. Two- to 3-year local control rates of stage I NSCLC with stereotactic body radiotherapy have ranged from 80% to 95%. Stereotactic body radiotherapy has been investigated in patients unfit to undergo surgery, with survival rates similar to surgical outcomes.

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

BREAST TUMORS
The treatment of small cancers of the breast has evolved from total mastectomy to 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 death, and local recurrence. Additionally, RFA can burn the skin and 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 (eg, RFA, microwave ablation) are being investigated.

MISCELLANEOUS TUMORS
RFA has been investigated for use in individuals with different lesions in different anatomic sites. These anatomic sites include, but are 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; further, these recurrent tumors are often untreatable with standard salvage therapies. Palliative chemotherapy or comfort measures may be offered. The safety and efficacy of RFA have been investigated as an option for palliative treatment in these situations.

RADIOFREQUENCY ABLATION
RFA was initially developed to treat inoperable tumors of the liver (see policy #286). 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).

Summary

In radiofrequency ablation (RFA), a probe is inserted into the center of a tumor; then, prong-shaped, noninsulated electrodes are projected into the tumor. Next, heat is generated locally by an alternating, high-frequency current that travels through the electrodes. The localized heat treats the tissue adjacent to the probe, resulting in a 3- 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 a local recurrence, it occurs at the edge and can sometimes be retreated. RFA may be performed percutaneously, laparoscopically, or as an open procedure.

Bone Tumors

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 population is comprised of patients with few or no treatment options, for whom short-term pain relief is an appropriate clinical outcome. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

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 during 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 symptom relief with minimal complications, for a population for whom short-term symptom relief and avoidance of invasive procedures are appropriate clinical outcomes. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Localized Renal Cell Carcinoma

For individuals who have localized renal cell carcinoma that is no more than 4 cm in size who receive RFA, the evidence includes a randomized controlled trial (RCT), numerous 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 I (≤7 cm across) renal tumors, found that the rate of local progression was greater with RFA than with nephrectomy. The differing meta-analytic results 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 obtained in 2010 supported use of 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 worsen kidney function substantially 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 Primary Pulmonary and Nonpulmonary Tumors
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 in size, RFA can lead to a complete response in as many as 88% of patients for at least 1 year. Two-year survival rates have been reported to range from 41% to 75% in case series, with 5-year survival rates of 20% to 27%. In general, the evidence suggests that 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.

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 permit comparisons with conventional breast-conserving procedures. Further studies, with long-term follow-up, should focus on whether RFA of the breast for small tumors 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 4 RCTs and 5 observational studies found significant reductions in nodule size and withdrawal from methimazole following treatment with RFA when compared with a variety of local treatment. Reports of complications vary. The most frequent major complication in 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 few 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 these tumor types. 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.

Policy History

Date	Action
10/2018	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
1/2018	Clarified coding information.
10/2017	New references added from BCBSA National medical policy.
10/2016	New references added from BCBSA National medical policy.
1/2016	Clarified coding information.
11/2015	New references added from BCBSA National medical policy.
12/2014	New references added from BCBSA National medical policy.
5/2014	Updated Coding section with ICD10 procedure and diagnosis codes. Effective 10/2015.
1/2014	New references added from BCBSA National medical policy.
6/2013	BCBSA National medical policy review.

	New investigational indications described. Effective 6/1/2013.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
10/2011	Reviewed - Medical Policy Group - Gastroenterology, Nutrition and Organ Transplantation. No changes to policy statements.
7/2011	Reviewed - Medical Policy Group - Hematology and Oncology. No changes to policy statements.
11/2010	Reviewed - Medical Policy Group - Gastroenterology, Nutrition and Organ Transplantation. No changes to policy statements.
9/2010	Reviewed - Medical Policy Group - Hematology and Oncology. No changes to policy statements.
9/2010	New policy effective 9/2010 describing ongoing covered and non-covered indications.
11/2009	National policy reviewed 11/2009. Revisions to coverage statement made. Effective 11/2009.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

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