

POLICY TITLE	RADIOFREQUENCY ABLATION OF MISCELLANEOUS SOLID TUMORS EXCLUDING LIVER TUMORS
POLICY NUMBER	MP-1.084

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I. POLICY

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.

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

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 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 <60mL/min/m²) **AND**
- The standard surgical approach (i.e. resection of renal tissue) is likely to substantially worsen kidney function; **OR**
- Patient is not considered a surgical candidate.

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:

- 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.

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

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

(See the Policy Guidelines section for additional criteria.)

Radiofrequency ablation is considered **investigational** as a technique for ablation of:

- breast tumors;
- lung cancer not meeting the criteria above;
- renal cell cancer not meeting the criteria above;
- osteoid osteomas that can be managed with medical treatment;
- painful bony metastases as initial treatment; and
- all other tumors outside the liver including, but not limited to, the head and neck, thyroid, adrenal gland, ovary, and pelvic/abdominal metastases of unspecified origin

There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure for these indications.

POLICY GUIDELINES

Radiofrequency Ablation (RFA) of the lung

The following are additional criteria that have been developed by clinical judgment or 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.

Cross-reference:

MP-1.055 Radiofrequency Ablation of Primary or Metastatic Liver Tumors

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital BlueCross please see additional information below, and subject to benefit variations as discussed in Section VI below.

FEP PPO - Refer to FEP Medical Policy Manual MP-7.01.95, Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors. The FEP Medical Policy Manual can be found at: <https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies>.

III. DESCRIPTION/BACKGROUND

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Radiofrequency Ablation

RFA was initially developed to treat inoperable tumors of the liver (see evidence review MP 1.055). 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).

Regulatory Status

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

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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.

IV. RATIONALE

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SUMMARY OF EVIDENCE

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. The 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. The 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), a large number of observational studies, and systematic reviews of these studies. The 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 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

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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.

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 observational studies and systematic reviews of these studies. The 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. The relevant outcomes are 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 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, case series, and systematic reviews of these studies. The 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 to a variety of local treatment. Reports of complications have varied. The most frequent major complication in a large multicenter series of specialty centers was voice change. The evidence is insufficient to determine the effects the of technology on health outcomes.

Miscellaneous Solid Tumors

For individuals who have miscellaneous tumors (e.g., head and neck, thyroid cancer, pancreas) who receive RFA, the evidence includes a few case series, prospective studies, and retrospective comparative studies. The relevant outcomes are change in disease status, quality of life, and treatment-related morbidity. There is a limited evidence base for each tumor type. Reporting on

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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 technology on health outcomes.

V. DEFINITIONS

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ADJUVANT refers to a substance, especially a drug, added to a prescription to assist in the action of the main ingredient.

ALKYLATING AGENT is any substance that contains an alkyl radical and is capable of replacing a free hydrogen atom in an organic compound. This type of chemical reaction results in interference with mitosis and cell division, especially in the proliferating tissue. The agents are especially helpful in the treatment of cancer.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital BlueCross' Provider Services or Member Services.

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VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational; therefore, not covered:

CPT Codes®							
41530	0404T						

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Covered when medically necessary:

CPT Codes®							
20982	32998	50592					

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ICD-10-CM Diagnosis Codes	Description
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
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
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C64.1	Malignant neoplasm of right kidney, except renal pelvis
C64.2	Malignant neoplasm of left kidney, except renal pelvis
C78.01	Secondary malignant neoplasm of right lung
C78.02	Secondary malignant neoplasm of left lung
C79.51	Secondary malignant neoplasm of bone

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ICD-10-CM Diagnosis Codes	Description
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
D16.11	Benign neoplasm of short bones of right upper limb
D16.12	Benign neoplasm of short bones of left upper limb
D16.21	Benign neoplasm of long bones of right lower limb
D16.22	Benign neoplasm of long bones of left 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

IX. REFERENCES

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X. POLICY HISTORY

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MP-1.084	CAC 3/30/04
	CAC 8/31/04
	CAC 9/27/05
	CAC 9/26/06
	CAC 9/25/07
	CAC 9/30/08
	CAC 5/26/09
	CAC 5/25/10 Consensus review.
	CAC 10/25/11 Adopt BCBSA. No change to guidelines.
	CAC 1/29/13 Minor review. Policy statements changed to indicate medically necessary options for primary and metastatic pulmonary tumors; reworded investigational policy statement and added thyroid as investigational example. References updated. Background information revised to reflect current indications. FEP variation added to refer to the FEP medical policy manual.

POLICY TITLE	RADIOFREQUENCY ABLATION OF MISCELLANEOUS SOLID TUMORS EXCLUDING LIVER TUMORS
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<p>CAC 1/28/14 Consensus review. References updated. No changes to the policy statements. Rationale added.</p>
<p>CAC 1/27/15 Consensus review. References and rationale updated. No change to policy statements. New 2015 code added to policy. Codes reviewed.</p>
<p>CAC 1/26/16 Consensus review. No change to policy statements. References and rationale updated. Coding reviewed and updated.</p>
<p>11/10/16 Administrative update. Variation reformatting.</p>
<p>CAC 1/31/17 Consensus review. Policy statements unchanged. Description/Background, Rationale and Reference sections updated. Coding reviewed.</p>
<p>1/02/18 Consensus review. Policy statements unchanged. Description/Background, Rationale and Reference sections updated.</p>
<p>11/28/18 Consensus review. No change to policy statements. Description/Background, and Reference sections updated. Rationale condensed.</p>
<p>10/2/19 Consensus review. Policy statements unchanged. Background, Rationale and Reference sections updated.</p>
<p>8/6/20 Consensus review. Policy statements unchanged. References updated.</p>

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