MEDICAL POLICY

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

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☒ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**3/1/2024**

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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:

- 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/m^2); **AND**
- The standard surgical approach (i.e. resection of renal tissue) is likely to substantially worsen kidney function; **OR**
- The 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**
- The 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.

Radiofrequency ablation may be considered **medically necessary** for the treatment of differentiated thyroid carcinoma (i.e. papillary, follicular or Hürthle) for metastatic disease OR locoregional recurrence in patients with limited burden nodal disease.

Radiofrequency ablation may be considered **medically necessary** for the treatment of distant metastases in recurrent or persistent medullary thyroid carcinoma.

(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;
- Thyroid carcinoma or thyroid tumors not meeting criteria above;
- 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

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

The National Comprehensive Cancer Network (NCCN) is a nonprofit alliance of cancer centers throughout the United States. NCCN develops the Clinical Practice Guidelines in Oncology which are recommendations aimed to help health care professionals diagnose, treat and manage patients with cancer. Guidelines evolve continuously as new treatments and diagnostics emerge and may be used by Capital Blue Cross when determining medical necessity according to this policy.

POLICY GUIDELINES

Radiofrequency Ablation (RFA) of the lung

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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
MP 1.088 Cryoablation of Tumors Located in the Kidney, Lung, Breast, Pancreas, or Bone
MP 7.027 Laparoscopic, Percutaneous, and Transcervical Techniques for Uterine Fibroid Myolysis

II. PRODUCT VARIATIONS Top

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

FEP PPO - Refer to FEP Medical Policy Manual. 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 Top

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).

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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 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 cohort study and case series. Relevant outcomes are symptoms, change in disease status, QOL, medication use, and treatment-related morbidity. A prospective cohort study and case series have shown clinically significant pain relief (defined as a decrease of 2 units from baseline on the Brief Pain Inventory scale) or reduction in opioid use following treatment of painful osteolytic metastases. A multicenter, prospective study reported significant reductions in pain through the 6-month follow-up period, with 59% of patients achieving immediate improvement in pain within 3 days of RFA. 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 an 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), numerous 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. A meta-analysis from 2022 found that PN was superior to ablation (RFA, cryoablation, and microwave ablation) in local recurrence. Overall complications, decline in renal function, and cancer-specific mortality rates did not differ between ablation and nephrectomy. 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.

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. 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, 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 that the technology results in an improvement in the net health outcome.

Thyroid Carcinoma
Thyroid carcinoma is uncommon with mortality rates being generally low. NCCN Thyroid Carcinoma guidelines list RFA as a potential treatment for select patients. The American Thyroid Association Management Guidelines (2015) for Adult Patients with Thyroid Nodules and Differentiated Thyroid Cancer notes that differentiated thyroid cancer, comprising the vast majority of all thyroid cancers, is becoming increasingly prevalent. Guidelines include radiofrequency ablation as one of the localized thermal ablative treatments as potentially beneficial in select patients with metastatic differentiated thyroid cancer.

Miscellaneous Solid Tumors
For individuals who have miscellaneous tumors (e.g., head and neck, 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 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

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 Top

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 Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross'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 Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

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:

Procedure Codes							
41530							

Covered when medically necessary:

Procedure Codes								
20982	32998	50542	50592					

ICD-10- CM Diagnosis Codes							
C34.01	C34.02	C34.11	C34.12	C34.2	C34.31	C34.32	C64.1
C64.2	C73	C78.01	C78.02	C79.51	D16.01	D16.02	D16.11
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IX. REFERENCES

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POLICY TITLE	RADIOFREQUENCY ABLATION OF MISCELLANEOUS SOLID TUMORS EXCLUDING LIVER TUMORS
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X. POLICY HISTORY

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MP-1.084	**8/6/20 Consensus review.** Policy statements unchanged. References updated.
	12/3/21 Minor review. Added as potentially medically necessary criteria for the treatment of both differentiated thyroid carcinoma and medullary thyroid carcinoma (previously investigational); FEP language updated; added NCCN statement; update diagnosis codes and references.
	12/19/2022 Consensus review. No changes to policy statement. Updated cross references, rationale, references. Removed code 0404T from INV and added code 50542 as MN.
	11/20/2023 Consensus review. No changes to policy statement. Updated references. Coding reviewed, no changes.

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