BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 7.01.95 Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors

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Related Policies:

6.01.10 - Stereotactic Radiosurgery and Stereotactic Body Radiotherapy
7.01.91 - Radiofrequency Ablation of Primary or Metastatic Liver Tumors
7.01.92 - Cryoablation of Tumors Located in the Kidney, Lung, Breast, Pancreas, or Bone

Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors

Description

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In radiofrequency ablation (RFA), a probe is inserted into the center of a tumor; then, prong-shaped, non-insulated 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 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 a local recurrence, it occurs at the edge and can sometimes be retreated. RFA may be performed percutaneously, laparoscopically, or as an open procedure.

OBJECTIVE

The objective of this evidence review is to determine whether the use of radiofrequency ablation improves the net health outcome in individuals with a range of tumors (including, osteolytic bone metastases, osteoid osteomas, renal cell carcinoma, lung cancer, breast tumors, and thyroid tumors, and others).

POLICY STATEMENT

Osteolytic bone metastases

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

Osteoid osteomas

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

Renal cell carcinoma

Radiofrequency ablation may be considered **medically necessary** to treat localized renal cell carcinoma that is no more than 4 cm in size when criteria 1 and 2 are met:

1. When it is necessary to preserve kidney function in individuals with significantly impaired renal function (ie, the individual has 1 kidney or renal insufficiency defined by a glomerular filtration rate of <60 mL/min/m^2);
2. When the standard surgical approach (ie, resection of renal tissue) is likely to worsen existing kidney function substantially; OR When the individual is not considered a surgical candidate.

Non-small-cell lung cancer

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 criteria 1 and 2 are met:

1. When surgical resection or radiotherapy with curative intent is considered appropriate based on stage of disease, however, medical comorbidity renders the individual unfit for those interventions;
2. When the tumor is located at least 1 cm from the trachea, main bronchi, esophagus, aorta, aortic arch branches, pulmonary artery, and the heart.

Nonpulmonary tumor(s) metastatic to the lung

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 criteria 1 and 2 are met:

1. When it is necessary to preserve lung function because surgical resection or radiotherapy is likely to worsen pulmonary status substantially; OR When the individual is not considered a surgical candidate;
2. When 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, pancreas, adrenal gland, ovary, and pelvic/abdominal metastases of unspecified origin.

POLICY GUIDELINES

The following are additional criteria developed by clinical judgment or consensus and existing guidelines for the use of radiofrequency ablation to treat metastatic tumors to the lung:

- 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.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA 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.

RATIONALE

Summary of Evidence

For individuals who have painful osteolytic bone metastases who have failed or are poor candidates for standard treatments who receive radiofrequency ablation (RFA) , the evidence includes a prospective cohort study and case series. Relevant outcomes are symptoms, change in disease status, quality of life (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 systematic reviews of these studies. Relevant outcomes are symptoms, change in disease status, QOL, medication use, and treatment-related morbidity. In a systematic review of thermal ablation techniques, clinical success (pain-free) was achieved in 94% to 98% of patients. Most patients (89% to 96%) remained pain-free when assessed during longer-term follow-up. Another systematic review reported similar success rates noting an average 8.3% failure rate among patients receiving computed tomography (CT) -guided RFA. 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 an improvement in the net health outcome.

For individuals who have localized renal cell carcinoma (RCC) 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 (OS) , change in disease status, QOL, 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 (PN) 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 PN. 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 that the technology results in an improvement in the net health outcome.

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 OS, change in disease status, QOL, 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 an improvement in the net health outcome.

For individuals who have breast tumors who receive RFA, the evidence includes observational studies and systematic reviews of these studies. Relevant outcomes are OS, change in disease status, QOL, and treatment-related morbidity. Evidence has reported varied and incomplete ablation rates with concerns about postablation tumor cell viability. Long-term improvements in health outcomes have not been demonstrated. Additionally, available studies do not permit comparisons with conventional breast-conserving procedures. Further prospective 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 that the technology results in an improvement in the net health outcome.

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 (PEI) 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.

For individuals who have miscellaneous tumors (eg, head and neck, thyroid cancer, pancreas) who receive RFA, the evidence includes a few case series, prospective observational studies, and retrospective comparative studies. Relevant outcomes are OS, change in disease status, QOL, 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 that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Chest Physicians

The American College of Chest Physicians (2013) guidelines on the treatment of stage I and II non-small-cell lung cancer (NSCLC) have indicated RFA has been used effectively in clinical stage I NSCLC.[72,] Therefore, in medically inoperable patients, peripheral NSCLC tumors less than 3 cm may be treated with RFA. The College also collaborated with the Society of Thoracic Surgeons to develop consensus guidelines on the treatment of high-risk patients with stage I NSCLC.[73,] These 2012 consensus guidelines indicated RFA is an alternative treatment option for patients who are not surgical candidates due to severe medical comorbidity.

American Head and Neck Society - Endocrine Surgery Section

An international, multidisciplinary consensus statement on RFA and related ultrasound-guided ablation technologies for the treatment of benign and malignant thyroid disease was released in 2022 through a collaboration of international professional societies, including the Endocrine Surgery Section of the American Head and Neck Society.[74,] Select relevant recommendations from the guideline are listed in Table 6.

Table 1. Summary of RFA Recommendations for Treatment of Benign and Malignant Thyroid Disease*

Recommendation 1	US-guided ablation procedures may be used as a first-line alternative to surgery for patients with benign thyroid nodules contributing to compressive and/or cosmetic symptoms.
Recommendation 2	Although less efficacious than surgery or RAI in normalizing thyroid function, thermal ablation procedures can be a safe therapeutic alternative in patients with an autonomously functional thyroid nodule and contraindications to first-line techniques.
Recommendation 3a	US-guided ablation procedures may be considered in patients with suitable primary papillary microcarcinoma who are unfit for surgery or decline surgery or active surveillance
Recommendation 3b	US-guided ablation procedures may be considered in patients with suitable recurrent papillary thyroid carcinoma who are unfit for surgery or decline surgery or active surveillance
Recommendation 3c	Repeat ablation of a benign nodule can be considered for remnant nodular tissue contributing to unresolved symptomatic or cosmetic concerns

*This is not a comprehensive list of recommendations from the guideline.
RAI: radioactive iodine; RFA: radiofrequency ablation; US: Ultrasound.

American Urological Association

The American Urological Association (AUA; 2017) guideline on renal masses and localized renal cancer affirms that partial nephrectomy should be prioritized for the management of cT1a renal masses when intervention is indicated.[75,] Thermal ablation should be considered "as an alternate approach for the management of cT1a renal masses <3 cm in size." The guidelines were updated in 2021 and recommendations are generally consistent with what was published in the 2017 guideline.[76,] The 2021 AUA guideline explicitly states that RFA and cryoablation may be offered as options to patients who elect thermal ablation.

American Thyroid Association

The American Thyroid Association (2015) guideline on the management of thyroid nodules and differentiated thyroid cancer provides recommendations for management. [48,] Patients with a benign cytology diagnosis or those very unlikely to be malignant (eg, purely cystic nodule) should undergo surveillance with the frequency determined by the level of suspicion for a missed malignancy. Medical or surgical intervention is considered if the nodules are large (>4 cm), causing compressive or structural symptoms, or if there is clinical concern. Recurrent cystic thyroid nodules with benign cytology should be considered for surgical removal or percutaneous ethanol injection. For differentiated thyroid cancer, "localized treatments with thermal (radiofrequency or cryo-) ablation, ethanol ablation, or chemoembolization may be beneficial in patients with a single or a few metastases and in those with metastases at high risk of local complications."

National Comprehensive Cancer Network

The National Comprehensive Cancer Network (NCCN) guidelines for the treatment of NSCLC (v.3.2023) state:[77,]. "For medically operable disease, resection is the preferred local treatment modality (other modalities include SABR [stereotactic ablative radiotherapy], thermal ablation such as radiofrequency ablation, and cryotherapy)." For patients who are not amenable to surgery, image-guided thermal ablation therapy (IGTA; includes RFA, microwave ablation, and cryoablation) may be considered. The guidance states "IGTA is an option for the management of NSCLC lesions <3 cm. Ablation for NSCLC lesions >3 cm may be associated with higher rates of local recurrence and complications."

The NCCN guidelines for thyroid carcinoma (v.3.2023) indicate that local therapies such as RFA may be considered for locoregional recurrence of thyroid carcinoma-papillary carcinoma in select patients with limited burden nodal disease. Additionally, local therapies, including RFA, can be

considered in those with metastatic disease.[78,]

The NCCN guidelines (v.1.2024) for renal cancer indicate that "thermal ablation (eg, cryosurgery, radiofrequency ablation, microwave ablation) is an option for the management of clinical stage T1 renal lesions. Thermal ablation is an option for clinical T1b masses in select patients not eligible for surgery. Biopsy of lesions is recommended to be done prior to or at time of ablation. Ablative techniques may require mutiple treatments to achieve the same oncologic outcomes as conventional surgery." [79,]

The NCCN colon cancer guidelines (v.2.2023) state that "resection is the standard approach for the local treatment of resectable metastatic disease. However, patients with liver or lung oligometastases can also be considered for tumor ablation therapy, particularly in cases that may not be optimal for resection."[80,] "There is extensive evidence on the use of RFA as a reasonable treatment option for non-surgical candidates and for recurrent disease after hepatectomy with small liver metastases that can be treated with clear margins."

The NCCN guidelines for head and neck cancers (v.2.2023) ,[81,] breast cancer (v.4.2023),[82,] bone cancer (v.1.2024),[83,] and pancreatic adenocarcinoma (v.2.2023) do not mention RFA.[84,]

National Institute for Health and Care Excellence

The NICE guidance (2004) on osteoid osteoma indicated that "current evidence on the safety and efficacy of computed tomography (CT)-guided thermocoagulation of osteoid osteoma appears adequate to support its use...."[85,]

Updated NICE guidance (2010) on renal cancer has indicated that "evidence on the safety and efficacy of percutaneous radiofrequency ablation (RFA) ... in the short and medium term appears adequate to support the use of this procedure provided that patients are followed up in the long term."[86,]

The NICE guidance (2010) on RFA for primary and secondary lung cancers has stated: "Current evidence on the efficacy of percutaneous radiofrequency ablation (RFA) ... is adequate in terms of tumor control."[87,] The NICE also indicated RFA might "be used in patients with small, early-stage lung cancers or small numbers of lung metastases who are unsuitable for, or prefer not to undergo, surgery. It may also have a place in multi-modality treatment of more advanced primary lung cancers." The guidance warned of serious complications (eg, pneumothorax) among lung cancer patients.

The NICE guidance (2016) on benign thyroid nodules stated: "Current evidence on the safety and efficacy of ultrasound-guided percutaneous radiofrequency ablation ... is adequate to support the use of this procedure...."[88,]

Society of Interventional Radiology

The Society of Interventional Radiology (2020) published a position statement on the role of percutaneous ablation in renal cell carcinoma.[89,] Their relevant recommendations are as follows:

- "In patients with small renal tumors (stage T1a), percutaneous thermal ablation is a safe and effective treatment with fewer complications than nephrectomy and acceptable long-term oncological and survival outcomes. (Level of Evidence: C; Strength of Recommendation: Moderate)"
- "In selected patients with suspected T1a renal cell carcinoma, percutaneous thermal ablation should be offered over active surveillance. (Level of Evidence: C; Strength of Recommendation: Moderate)"
- "In high-risk patients with T1b renal cell carcinoma who are not surgical candidates, percutaneous thermal ablation may be an appropriate treatment option; however, further research in this area is required. (Level of Evidence: D; Strength of Recommendation: Weak)"
- "Radiofrequency ablation, cryoablation, and microwave ablation are all appropriate modalities for thermal ablation, and method of ablation should be left to the discretion of the operating physician. (Level of Evidence: D; Strength of Recommendation: Weak)"

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
June 2012	New policy	Medically necessary with criteria for: osteolytic bone metastases, osteoid osteomas, localized renal cell carcinoma, isolated peripheral NSCLC, malignant nonpulmonary tumors metastatic to lung; investigational for: breast tumors, lung, renal, osteoid osteomas, and bony metastases not meeting criteria and all other tumors.
March 2013	Replace policy	Policy updated with literature review, reworded not medically necessary policy statement and added thyroid as not medically necessary. References 12, 19, 29, 42, 50-52, 59, 62-63 added. Other references deleted.
March 2014	Replace policy	Policy updated with literature review, Policy statements unchanged. References added, renumbered or removed.
March 2015	Replace policy	Policy updated with literature review; references 4, 48, and 56 added; other references deleted. Policy statements unchanged
December 2016	Replace policy	Policy updated with literature review; reference 13 added; references 54- 56 updated; some references removed. Policy statements unchanged.
December 2017	Replace policy	Policy updated with literature review through July 20, 2017; reference 59 added. Policy statements unchanged.
December 2018	Replace policy	Policy updated with literature review through July 26, 2018; references 5- 7, 15-19, 31, 34-35, 40, 42, and 50 added. Policy statements unchanged.
September 2019	Replace policy	Policy updated with literature review through July 8, 2019; references added, references on NCCN updated. Policy statements unchanged.
December 2020	Replace policy	Policy updated with literature review through July 27, 2020; references added. Policy statements unchanged.
December 2021	Replace policy	Policy updated with literature review through July 28, 2021; references added. Policy statements unchanged.
December 2022	Replace policy	Policy updated with literature review through August 10, 2022; references added. Minor editorial refinements to policy statements; intent unchanged.
December 2023	Replace policy	Policy updated with literature review through August 7, 2023; no references added. Policy statements unchanged.