

## MEDICAL POLICY – 7.01.95

# Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors

BCBSA Ref. Policy: 7.01.95

Effective Date: Dec. 1, 2024

Last Revised: Jan. 1, 2025

Replaces: 7.01.540

## RELATED MEDICAL POLICIES:

7.01.92 Cryosurgical Ablation of Miscellaneous Solid Tumors Other Than Liver, Prostate, or Dermatologic Tumors


8.01.24 Hematopoietic Cell Transplantation for Miscellaneous Solid Tumors in Adults

8.01.505 Transcatheter Arterial Chemoembolization as a Treatment for Primary or Metastatic Liver Malignancies

8.01.521 Radioembolization for Primary and Metastatic Tumors of the Liver

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## Introduction

Radiofrequency ablation (RFA) is a way to destroy a tumor. A probe is placed in the center of a tumor. Small areas at the end of the probe, called electrodes, carry electrical current. The electrical current flows from the electrodes and heats up nearby tissue. The heat is hot enough to destroy the tumor. The body naturally replaces the treated tissue with fibrous or scar tissue. This policy describes when RFA may be considered medically necessary for specific types of tumors, including lung and kidney tumors meeting certain criteria.

**Note:** The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

## Policy Coverage Criteria

**Note: Radiofrequency ablation of primary or metastatic liver tumors is considered standard treatment and does not require medical necessity review**

| Service                 | Medical Necessity   |
|-------------------------|---|
| Radiofrequency ablation | <p><b>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.</b></p> <p><b>Radiofrequency ablation may be considered medically necessary to treat osteoid osteomas that cannot be managed successfully with medical treatment.</b></p> <p><b>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:</b></p> <ul style="list-style-type: none"> <li>• When it is necessary to preserve kidney function in individuals with significantly impaired renal function (i.e., the individual has 1 kidney or renal insufficiency defined by a glomerular filtration rate of less than 60 mL/min/m<sup>2</sup>)</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>○ When the standard surgical approach (i.e., resection of renal tissue) is likely to worsen existing kidney function substantially</li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>• The individual is not considered a surgical candidate</li> </ul> <p><b>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:</b></p> <ul style="list-style-type: none"> <li>• 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</li> </ul> <p><b>AND</b></p> |



| Service | Medical Necessity   |
|---------|---|
|         | <ul style="list-style-type: none"> <li>When the tumor is located at least 1 cm from the trachea, main bronchi, esophagus, aorta, aortic arch branches, pulmonary artery and the heart</li> </ul> <p><b>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:</b></p> <ul style="list-style-type: none"> <li>When it is necessary to preserve lung function because surgical resection or radiotherapy is likely to worsen pulmonary status substantially</li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>When the individual is not considered a surgical candidate</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>When there is no evidence of extra pulmonary metastases</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>When the tumor is located at least 1 cm from the trachea, main bronchi, esophagus, aorta, aortic arch branches, pulmonary artery and the heart</li> </ul> <p><b>Note:</b> The following are additional criteria developed by clinical judgment or consensus and existing guidelines for the use of radiofrequency ablation in metastatic tumors to the lung:</p> <ul style="list-style-type: none"> <li>No more than 3 tumors per lung should be ablated</li> <li>Tumors should be amenable to complete ablation;</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>Twelve months should elapse before a repeat ablation is considered.</li> </ul> |

| Service                               | Investigational  |
|---------------------------------------|--|
| <p><b>Radiofrequency ablation</b></p> | <p><b>Radiofrequency ablation is considered investigational as a technique for ablation of:</b></p> <ul style="list-style-type: none"> <li>Breast tumors</li> <li>Lung cancer not meeting the criteria above</li> <li>Renal cell cancer not meeting the criteria above</li> <li>Osteoid osteomas that can be managed with medical treatment</li> <li>Painful bony metastases as initial treatment</li> </ul> |



| Service | Investigational   |
|---------|---|
|         | <ul style="list-style-type: none"> <li>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</li> </ul> |

**Documentation Requirements**

**The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:**

- Detailed history and physical with relevant documentation of:
  - Type of malignancy diagnosis
  - Medical/radiation treatment tried

**In addition, for:**

- Renal cell carcinoma** that is less than or equal to 4 cm in size and ONE of the following:
  - Documentation that individual has 1 kidney OR renal insufficiency as defined by a glomerular filtration rate of less than 60 mL/min/m<sup>2</sup>

**AND**

  - Resection of renal tissue is likely to worsen existing kidney function

**OR**

  - Individual is not considered a surgical candidate
- Isolated peripheral non-small-cell lung cancer** lesion that is no more than 3 cm in size and ALL of the following:
  - Surgical or radiotherapy with curative intent is considered appropriate based on stage of disease, however medical co-morbidity renders the individual unfit for those interventions

**AND**

  - Tumors are located at least 1 cm from the trachea, main bronchi, esophagus, aorta, aortic arch branches, pulmonary artery and the heart
- Malignant nonpulmonary tumor(s) metastatic to the lung** that are no more than 3 cm in size and ALL of the following:
  - Documentation that it is necessary to preserve lung function because surgical resection or radiotherapy is likely to worsen pulmonary status

**OR**

  - Individual is not considered a surgical candidate

**AND**

  - There is no evidence of extra pulmonary metastases



## Documentation Requirements

### AND

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

## Coding

| Code       | Description  |
|------------|--|
| <b>CPT</b> |  |
| 20982      | Ablation therapy for reduction or eradication of 1 or more bone tumors (e.g., metastasis) including adjacent soft tissue when involved by tumor extension, percutaneous, including imaging guidance when performed; radiofrequency |
| 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   |
| 50592      | Ablation, 1 or more renal tumor(s), percutaneous, unilateral, radiofrequency   |
| 60660      | Ablation of 1 or more thyroid nodule(s), one lobe or the isthmus, percutaneous, including imaging guidance, radiofrequency (new code effective 01/01/25)   |
| 60661      | Ablation of 1 or more thyroid nodule(s), additional lobe, percutaneous, including imaging guidance, radiofrequency (List separately in addition to code for primary procedure) (new code effective 01/01/25)                       |

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

## Related Information

N/A

## Evidence Review



## Description

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 centimeters (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 can sometimes be retreated. RFA may be performed percutaneously, laparoscopically, or as an open procedure.

## Background

### Health Disparities in Certain Solid Tumor Types

Based on data from 2014 through 2018, age-adjusted breast cancer mortality is approximately 40% higher among Black women compared to non-Hispanic White women in the United States (US) (27.7 vs 20.0 deaths per 100,000 women), despite a lower overall incidence of breast cancer among Black women (125.8 vs 139.2 cases per 100,000 women).<sup>1</sup> Experts postulate that this divergence in mortality may be related to access issues— Black women are more likely than White women to lack health insurance, limiting access to screening and appropriate therapies. Socioeconomic status is also a driver in health and health outcome disparities related to breast cancer.<sup>2</sup> Women with low incomes have significantly lower rates of breast cancer screening, a higher probability of late-stage diagnosis, and are less likely to receive high-quality care, resulting in higher mortality from breast cancer.

Based on data from 2017 through 2021, kidney cancer is more common in men than women and occurs more often in American Indian and Alaskan Native individuals, followed by Black and Hispanic individuals.<sup>3</sup> American Indians and Alaska Natives have higher death rates from kidney cancer than any other racial or ethnic group. A cohort study by Howard et al (2021) included 158,445 patients with localized kidney cancer from the National Cancer Database between 2010 and 2017.<sup>4</sup> Investigators found that female patients were treated more aggressively compared with male patients, with lower adjusted odds of undertreatment and higher adjusted odds of overtreatment. They also found that Black and Hispanic patients had higher adjusted odds of undertreatment and overtreatment compared to White patients, and uninsured status was associated with lower adjusted odds of overtreatment and higher adjusted odds of undertreatment. These results suggest that sex, race and ethnicity, and socioeconomic status are



associated with disparities in guideline-based treatment for localized kidney cancer, specifically, with increased rates of non-guideline-based treatment for women and Black and Hispanic patients.

## Radiofrequency Ablation

RFA was initially developed to treat inoperable tumors of the liver. 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 (e.g., preserving normal organ tissue, decreasing morbidity, decreasing length of hospitalization).

Goals of RFA may include:

- Controlling local tumor growth and preventing recurrence;
- Palliating symptoms; and
- 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). 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 (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), and secondary tumors (if cells seed during probe removal).

## Osteolytic Bone Metastases

After lung and liver, bone is the third most common site of metastases and is relatively frequent among individuals 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 individuals, 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 (e.g., 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 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 individuals 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 its 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 (CT)-guided 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 individuals with pain despite medical management. However, a substantial incision may be necessary, with 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 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; further, individuals 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 (PN) 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 individuals. Alternative therapy such as RFA is of interest in individuals with small renal tumors when preservation of renal function is necessary (e.g., in individuals with marginal renal function, a solitary kidney, bilateral tumors) and in individuals with comorbidities that would render them unfit for surgery. Another consideration would be in individuals at high risk of developing additional renal cancers (e.g., von Hippel-Lindau disease).

## Primary Pulmonary and Nonpulmonary Tumors

Surgery is the current treatment of choice in individuals with stage 1 primary non-small-cell lung cancer (NSCLC; stage 1 includes 1a [T1N0M0] and 1b [T2N0M0]). Approximately 20% of individuals 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 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 1 individuals, with 5-year overall survival rates ranging from 77% for small T1 tumors to 35% for large T2 tumors. Untreated, stage 1 NSCLC has a 5-year overall survival rate range from 6% to 14%.

Individuals with early-stage NSCLC who are not surgical candidates may be candidates for radiotherapy with curative intent. In 2 large retrospective radiotherapy series, individuals with inoperable disease treated with definitive radiotherapy achieved 5-year survival rates of 10%



and 27%. In both studies, individuals 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-year to 3-year local control rates of stage 1 NSCLC with stereotactic body radiotherapy have ranged from 80% to 95%. Stereotactic body radiotherapy has been investigated in individuals unfit to undergo surgery, with survival rates similar to surgical outcomes.

RFA is also being investigated in individuals 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 individual'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 do damage to muscle, possibly limiting use in individuals 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 (e.g., 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, thyroid, pancreas, head and neck.



## Head and Neck Cancer

In individuals 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 has been investigated as an option for palliative treatment in these situations.

## Summary of Evidence

### Bone Tumors

For individuals with painful osteolytic bone metastases who have failed or are poor candidates for standard treatments who receive RFA, the evidence includes a prospective cohort study and case series. The 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) and 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 individuals achieving immediate improvement in pain within 3 days of RFA. The population is comprised of individuals with few to 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 individuals. Most individuals (89%-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 individuals receiving 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. 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 the 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 individual population. The evidence is insufficient to determine that the effects of the technology results in an improvement in the net health outcome.

For individuals with 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, RFA can lead to a complete response in as many as 88% of individuals for at least one year. Two-year survival rates have been reported to range from 41% to 75% in case series, with five-year survival rates of 20% to 27%. In general, the evidence suggests that RFA results in adequate survival and tumor control in individuals 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 with breast tumors 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. 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 comparable 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 with benign thyroid tumors who receive RFA, the evidence includes RCTs, prospective studies, 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. 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 and a 2024 review indicating durability up to 5 years. 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 the 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 individuals 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 with miscellaneous tumors (e.g., head and neck, thyroid cancer, pancreas) who receive RFA, the evidence includes a few case series, prospective observational studies, and retrospective comparative studies. The 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 that the technology results in an improvement in the net health outcome.

### Ongoing and Unpublished Clinical Trials

A currently ongoing trial that might influence this review is listed in [Table 1](#).

**Table 1. Summary of Key Trials**

| NCT No.                     | Trial Name   | Planned Enrollment | Completion Date |
|-----------------------------|--|--------------------|-----------------|
| <b>Ongoing</b>              |  |                    |                 |
| <a href="#">NCT05189821</a> | RFA Treatment for Papillary Thyroid Microcarcinoma Cohort              | 50                 | Nov 2026        |
| <a href="#">NCT05189808</a> | Radiofrequency Ablation for Indeterminate Bethesda III Thyroid Nodules | 50                 | Aug 2026        |



| NCT No.                     | Trial Name  | Planned Enrollment | Completion Date      |
|-----------------------------|---|--------------------|----------------------|
| <a href="#">NCT03808779</a> | A Multicenter, Randomized and Controlled Trial of Radiofrequency Ablation vs. Conventional Surgery as Treatment of Papillary Thyroid Microcarcinoma (PTMC)                          | 200                | Feb 2024             |
| <b>Unpublished</b>          |   |                    |                      |
| <a href="#">NCT04619472</a> | A Multicenter, Single Group Target Value Clinical Study to Evaluate Safety and Effectiveness of Radiofrequency Ablation System in the Treatment of Peripheral Lung Tumors           | 126                | Mar 2023             |
| <a href="#">NCT01051037</a> | Phase II Study Evaluating Safety and Efficacy of Stereotactic Body Radiotherapy and Radiofrequency Ablation for Medically Inoperable and Recurrent Lung Tumors Near Central Airways | 17                 | Dec 2017 (completed) |

NCT: national clinical trial.

## Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

### 2010 Input

In response to requests, input was received from two physician specialty societies (four reviewers) and two academic medical centers (four reviewers) while this policy was under review in 2010. Input was similar to that received in 2009, except support for use of RFA to treat lung tumors was declined (only one respondent indicated this was an option in tumors metastatic to lung). One respondent also indicated a potential use for adrenal tumors. Input supported RFA for localized renal cell carcinoma no more than 4 cm in size when preservation of kidney function is necessary, and a standard surgical approach would likely substantially worsen kidney function or when the individual is not considered a surgical candidate.



## 2009 Input

In response to requests, input was received from one physician specialty society (four reviews) and from two academic medical centers (three reviews) while this policy was under review in 2009. All reviewers supported the use of RFA in the treatment of painful bone metastases that have failed standard treatment and in the treatment of osteoid osteomas. Reviewers were divided over the use of RFA for lung tumors, although several agreed that, while it may be useful in a select population of individuals, it should be used in the clinical trial setting. Reviewers were also split with regard to RFA in the treatment of renal tumors, with some supporting its use in a select population of individuals. With the exception of one disagreement and one nonresponse, the reviewers agreed to the investigational statement on the use of RFA in all other tumors outside the liver that are addressed in this policy.

## Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion 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 guidelines (2013) on the treatment of stage I and II NSCLC have indicated radiofrequency ablation (RFA) has been used effectively in clinical stage I NSCLC.<sup>73</sup> Therefore, in medically inoperable individuals, 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 individuals with stage I NSCLC.<sup>74</sup> These 2012 consensus guidelines indicated RFA is an alternative treatment option in individuals 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.<sup>75</sup> Select relevant recommendations from the guideline are listed in [Table 2](#).

**Table 2. 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 3 <sup>a</sup> | 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 3 <sup>b</sup> | 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 3 <sup>c</sup> | 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 management of cT1a renal masses when intervention is indicated.<sup>76</sup> 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.<sup>77</sup> 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 management of thyroid nodules and differentiated thyroid cancer provides recommendations for management.<sup>49</sup> Individuals with a benign cytology diagnosis or those very unlikely to be malignant (e.g., 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 individuals 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 non-small cell lung cancer (v.2.2024) state<sup>78</sup>:

"For medically operable disease, resection is the preferred local treatment modality (other modalities include SABR, thermal ablation such as radiofrequency ablation and cryotherapy)." For individuals 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.3.2024) indicate that local therapies such as RFA may be considered for locoregional recurrence of thyroid carcinoma-papillary carcinoma in select individuals with limited burden nodal disease. Additionally, local therapies, including RFA, can be considered in those with metastatic disease.<sup>79</sup>

The NCCN guidelines (v.1.2025) for renal cancer indicate that "thermal ablation (e.g., cryosurgery, radiofrequency 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 multiple treatments to achieve the same oncologic outcomes as conventional surgery."<sup>80</sup>



The NCCN colon cancer guidelines (v.4.2024), state that “resection is the standard approach for the local treatment of resectable metastatic disease. However, individuals with liver or lung oligometastases can also be considered for tumor ablation therapy, particularly in cases that may not be optimal for resection.”<sup>81</sup> There is extensive evidence on the use of RFA as a reasonable treatment option for non-surgical candidates and those with recurrent disease after hepatectomy with small liver metastases that can be treated with clear margins.”

The NCCN guidelines for head and neck cancers (v.4.2024)<sup>82</sup>, breast cancer (v.4.2024)<sup>83</sup>, bone cancer (v.2.2024)<sup>84</sup>, and pancreatic adenocarcinoma (v.2.2024) do not mention RFA<sup>85</sup>.

## National Institute for Health and Care Excellence

The NICE guidance (2004) on osteoid osteoma has indicated that “current evidence on the safety and efficacy of CT-guided thermocoagulation of osteoid osteoma appears adequate to support its use...”<sup>86</sup>

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 individuals are followed up in the long term.”<sup>87</sup>

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.”<sup>88</sup> NICE also indicated RFA might “be used in individuals 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 (e.g., pneumothorax) among lung cancer individuals.

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...”<sup>89</sup>

## Society of Interventional Radiology

The Society of Interventional Radiology (2020) published a position statement on the role of percutaneous ablation in renal cell carcinoma.<sup>90</sup> 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)"

## Medicare National Coverage

There is no national coverage determination.

## Regulatory Status

The US 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.

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## History

| Date     | Comments   |
|----------|--|
| 12/11/12 | New policy. This policy replaces 7.01.540. Policy updated with literature review, reworded investigational policy statement and added thyroid as investigational. References 12, 19, 29, 42, 50-53, 59, 62-63 added. Other references deleted.   |
| 07/16/13 | Update Related Policies. Add 8.01.528.   |
| 12/09/13 | Replace policy. Note added to Policy stating "Radiofrequency ablation of liver tumors is not subject to medical review". Related policies 8.01.521, 8.01.505 added. Policy Guidelines reformatted for usability with coding more clearly detailed. Rationale updated with literature review through August 2013. References 24-25, 38-39, 52 added; others renumbered/removed. Policy statements unchanged, note added for |





| Date     | Comments   |
|----------|--|
|          | clarification. CPT codes 47380 and 47382 removed from policy; these procedures are not addressed in this policy.   |
| 03/11/14 | Coding Update. Codes 55.32, 55.34 and 55.35 were removed per ICD-10 mapping project; these codes are not utilized for adjudication of policy.  |
| 09/03/14 | Interim review. Revised note in policy stating: Radiofrequency ablation of liver tumors is not addressed in this policy and does require medical review. ICD-9 and ICD-10 diagnosis and procedure codes removed; these are not utilized in adjudication of the policy. |
| 12/17/14 | Annual Review. Policy updated with literature review through September 18, 2014; policy statements unchanged. References 13, 18-19 and 47 added.   |
| 11/10/15 | Annual Review. Policy updated with literature review through July 28, 2015; references 4, 48, and 56 added; other references deleted. Policy statements unchanged.   |
| 11/01/16 | Annual Review, approved October 11, 2016. Policy updated with literature review through July 26, 2016; references 13 and 34 added; references 54-56 updated; some references removed. Policy statements unchanged.   |
| 11/24/16 | Updated Related Policies, removed 8.01.528 as it was archived.   |
| 11/01/17 | Annual Review, approved October 19, 2017. Policy updated with literature review through July 20, 2017; reference 59 added. Policy statements unchanged.  |
| 12/01/18 | Annual Review, approved November 6, 2018. Policy updated with literature review through July 2018; references 5-7, 15-19, 31, 34-35, 40, 42, and 50 added. Policy statements unchanged.  |
| 12/01/19 | Annual Review, approved November 6, 2019. Policy updated with literature review through July 2019; references added, references on NCCN updated. Policy statements unchanged.  |
| 04/01/20 | Delete policy, approved March 10, 2020. This policy will be deleted effective July 2, 2020, and replaced with InterQual criteria for dates of service on or after July 2, 2020.  |
| 05/06/20 | Interim Review, approved May 5, 2020. This policy is reinstated immediately and will no longer be deleted or replaced with InterQual criteria on July 2, 2020.   |
| 07/14/20 | Coding update. CPT code 50542 added to this policy.  |
| 08/01/20 | Update Related Policies. 8.01.521 is now 8.01.43.  |
| 12/01/20 | Annual Review, approved November 3, 2020. Policy updated with literature review through July 27, 2020; references added. Policy statements unchanged.  |
| 12/01/21 | Annual Review, approved November 2, 2021. Policy updated with literature review through July 28, 2021; references added. Policy statements unchanged.  |
| 01/01/22 | Coding update, added new code 0673T.   |
| 06/01/22 | Coding update. Removed CPT code 0673T.   |



| Date     | Comments   |
|----------|--|
| 12/01/22 | Annual Review, approved November 7, 2022. Policy updated with literature review through August 10, 2022; references added. Minor editorial refinements to policy statements; intent unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization. |
| 06/15/23 | Update to Related Policies. 8.01.43 is replaced with 8.01.521 Radioembolization for Primary and Metastatic Tumors of the Liver.  |
| 12/01/23 | Annual Review, approved November 6, 2023. Policy updated with literature review through August 7, 2023; no references added. Policy statements unchanged.  |
| 12/01/24 | Annual Review, approved November 11, 2024. Policy updated with literature review through July 31, 2024; reference added. Policy statements unchanged.  |
| 01/01/25 | Coding update. Added new CPT codes 60660 and 60661.  |

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2025 Premera All Rights Reserved.

**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

