MEDICAL POLICY – 7.01.95
Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors

BCBSA Ref. Policy: 7.01.95
Effective Date: Dec. 1, 2018
Last Revised: Nov. 6, 2018
Replaces: 7.01.540

RELATED MEDICAL POLICIES:
7.01.526  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

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
<table>
<thead>
<tr>
<th>Service</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiofrequency ablation</td>
<td>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: • When it is necessary to preserve kidney function in patients with significantly impaired renal function (ie, the patient has 1 kidney or renal insufficiency defined by a glomerular filtration rate of less than 60 mL/min/m²) AND o When the standard surgical approach (ie, resection of renal tissue) is likely to worsen existing kidney function substantially 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: • 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 AND • When the tumor is located at least 1 cm from the trachea, main bronchi, esophagus, aorta, aortic arch branches, pulmonary...</td>
</tr>
</tbody>
</table>
Service | Medical Necessity
--- | ---
 | artery and the heart

**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:**

- When it is necessary to preserve lung function because surgical resection or radiotherapy is likely to worsen pulmonary status substantially

**OR**

- When the patient is not considered a surgical candidate

**AND**

- When there is no evidence of extra pulmonary metastases

**AND**

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

**Note:** 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:

- 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.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Investigational</th>
</tr>
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</table>
| **Radiofrequency ablation** | **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
- 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 |
Documentation Requirements

The patient’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 patient has 1 kidney OR renal insufficiency as defined by a glomerular filtration rate of less than 60 mL/min/m²
    - **AND**
      - Resection of renal tissue is likely to worsen existing kidney function
    - **OR**
      - Patient 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 patient 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**
    - Patient is not considered a surgical candidate
  - **AND**
    - There is no evidence of extra pulmonary 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
Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>CPT</td>
<td></td>
</tr>
<tr>
<td>20982</td>
<td>Ablation, bone tumor(s) (e.g., osteoid osteoma, metastasis) radiofrequency, percutaneous</td>
</tr>
<tr>
<td>32998</td>
<td>Ablation therapy for reduction or eradication of 1 or more pulmonary tumor(s) including pleura or chest wall when involved by tumor extension, percutaneous, radiofrequency, unilateral</td>
</tr>
<tr>
<td>50592</td>
<td>Ablation, 1 or more renal tumor(s), percutaneous, unilateral, radiofrequency</td>
</tr>
</tbody>
</table>

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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 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

*Osteolytic Bone Metastases*

After lung and liver, bone is the third most common site of metastases and is relatively common among patients with primary malignancies of the breast, prostate, and lung. Bone metastases often cause osteolysis (bone breakdown), resulting in pain, fractures, decreased mobility, and reduced quality of life.

**Treatment**

External-beam irradiation often is the initial palliative therapy for osteolytic bone metastases. However, pain from bone metastases is refractory to radiotherapy in 20% to 30% of patients, while recurrent pain at previously irradiated sites may be ineligible for additional radiation due to risks of normal tissue damage. Other alternatives include hormonal therapy, radiopharmaceuticals (eg, strontium 89), and bisphosphonates. Less often, surgery or chemotherapy may be used for palliation, and intractable pain may require opioid medications. Radiofrequency ablation (RFA) has been investigated as 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 patients between 5 and 20 years of age. Osteomas are most common in the lower extremity (usually the long bones, mainly the femur) and less common in the spine. These tumors typically have a characteristic clinical presentation and radiologic appearance, with pain, usually continuous and worse at night, and usually relieved by aspirin or other nonsteroidal anti-inflammatory drugs. The natural history of the osteoid osteoma varies based on 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–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 patients 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, patients may immediately walk on the treated extremity and return to daily activities when the anesthetic effect wears off. The risk of recurrence with RFA of an osteoma is 5% to 10%, and recurrent tumors can be retreated with RFA. In general, RFA is not performed in many spinal osteomas because of possible thermal-related nerve damage.

Localized Renal Cell Carcinoma

Radical nephrectomy remains the principal treatment of renal cell carcinoma; however, partial nephrectomy or nephron-sparing surgery has been shown to be as effective as radical nephrectomy, with comparable long-term recurrence-free survival rates, in a select group of patients. Alternative therapy such as RFA is of interest in patients with small renal tumors when preservation of renal function is necessary (eg, in patients with marginal renal function, a solitary kidney, bilateral tumors) and in patients with comorbidities that would render them unfit for surgery. Another consideration would be in patients at high risk of developing additional renal cancers (eg, von Hippel-Lindau disease).

Primary Pulmonary and Nonpulmonary Tumors

Surgery is the current treatment of choice in patients with stage 1 primary non-small-cell lung cancer (NSCLC; stage 1 includes 1a [T1N0M0] and 1b [T2N0M0]). Approximately 20% of patients 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 computed
tomography 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 patients, 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%.

Patients with early-stage NSCLC who are not surgical candidates may be candidates for radiotherapy with curative intent. In 2 large retrospective radiotherapy series, patients with inoperable disease treated with definitive radiotherapy achieved 5-year survival rates of 10% and 27%. In both studies, patients with T1N0 tumors had better 5-year survival rates of 60% and 32%, respectively.

Stereotactic body radiotherapy has gained more widespread use as a treatment option because it is a high-precision mode of therapy that delivers very high doses of radiation. Two-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 patients unfit to undergo surgery, with survival rates similar to surgical outcomes.

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

Breast Tumors

The treatment of small cancers of the breast has evolved from total mastectomy to more conservative treatment options such as lumpectomy, with more acceptable cosmetic outcomes and preservation of the breast. The selection of surgical approach balances the patient’s desire for breast conservation and the need for tumor-free margins in resected tissue. Minimally invasive nonsurgical techniques such as RFA are appealing if they can produce local control and survival equivalent to breast-conserving surgical alternatives. Nonsurgical ablative techniques pose difficulties such as the inability to determine tumor size, complete tumor cell death, and local recurrence. Additionally, RFA can burn the skin and do damage to muscle, possibly limiting use in patients with tumors near the skin or chest wall.
Thyroid Tumors

Surgical resection is the primary treatment choice for medically unresponsive, symptomatic benign thyroid tumors and thyroid carcinomas. However, techniques for ablation of thyroid tumors (eg, RFA, microwave ablation) are being investigated.

Miscellaneous Tumors

RFA has been investigated for use in individuals with a number of different lesions in different anatomic sites. These anatomic sites include, but are not limited to, the breast, head and neck.

Head and Neck Cancer

In patients with head and neck cancer with recurrent disease, surgical salvage attempts are poor in terms of local control, survival, and quality of life; further, these recurrent tumors are often untreatable with standard salvage therapies. Palliative chemotherapy or comfort measures may be offered. The safety and efficacy of RFA has been investigated as an option for palliative treatment in these situations.

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 benefits common to any minimally invasive procedure (eg, preserving normal organ tissue, decreasing morbidity, decreasing length of hospitalization).

Goals of RFA may include (1) controlling local tumor growth and preventing recurrence; (2) palliating symptoms; and (3) extending survival duration for patients with certain tumors. The effective volume of RFA depends on the frequency and duration of applied current, local tissue characteristics, and probe configuration (eg, single vs multiple tips). RFA can be performed as an open surgical procedure, laparoscopically or percutaneously, with ultrasound or computed tomography guidance.
Potential complications associated with RFA include those caused by heat damage to normal tissue adjacent to the tumor (eg, intestinal damage during RFA of kidney), structural damage along the probe track (eg, pneumothorax as a consequence of procedures on the lung), and secondary tumors (if cells seed during probe removal).

Summary 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 case series. Relevant outcomes are symptoms, change in disease status, quality of life, medication use, and treatment-related morbidity. Case series have shown clinically significant pain relief and reduction in opioid use following treatment of painful osteolytic metastases. The population is comprised of patients with few 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 a meaningful improvement in the net health outcome.

For individuals with painful osteoid osteomas who receive RFA, the evidence includes numerous observational studies and a systematic review of these studies. Relevant outcomes are symptoms, change in disease status, quality of life, medication use, and treatment-related morbidity. In a systematic review of thermal ablation techniques, clinical success (pain free) was achieved in 94% to 98% of patients. Most patients (89%-96%) remained pain free when assessed during longer term follow-up. Although no randomized trials of RFA for osteoid osteomas have been performed, the uncontrolled studies have demonstrated RFA can provide adequate symptom relief with minimal complications, for a population for whom short-term symptom relief and avoidance of invasive procedures are appropriate clinical outcomes. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

**Localized Renal Cell Carcinoma**

For individuals with localized renal cell carcinoma that is no more than 4 cm in size who receive RFA, the evidence includes a randomized controlled trial (RCT), numerous observational studies, and systematic reviews of these studies. Relevant outcomes are overall survival, change in disease status, quality of life, and treatment-related morbidity. A recent meta-analysis that
included only an RCT and cohort studies found that RFA was as effective as nephrectomy for small renal tumors, with a reduction in complications. Another recent meta-analysis, which included case series of stage 1 (≤7 cm across) renal tumors, found that the rate of local progression was greater with RFA than with nephrectomy. The differing meta-analytic results may be due to differences in tumor size in selected studies as well as potential selection bias when evaluating case series. Although inconsistent, the evidence does suggest that for small renal tumors, RFA may result in a similar rate of disease progression with a lower complication rate than nephrectomy. However, comparative trials are needed to determine with greater certainty the effects of these treatments in the same patient population. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Inoperable Primary Pulmonary Tumors and Nonpulmonary Metastases**

For individuals with inoperable primary pulmonary tumors or nonpulmonary tumors metastatic to the lung who receive RFA, the evidence includes observational studies and systematic reviews of these studies. 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 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 with breast tumors who receive RFA, the evidence includes observational studies and systematic reviews of these studies. Relevant outcomes are overall survival, change in disease status, quality of life, and treatment-related morbidity. Evidence has reported varied and incomplete ablation rates with concerns about postablation tumor cell viability. Long-term improvements in health outcomes have not been demonstrated. Additionally, available studies do not permit comparisons with conventional breast-conserving procedures. Further studies, with long-term follow-up, should focus on whether RFA of the breast for small tumors can provide local control and survival rates comparable with conventional breast-conserving treatment. The evidence is insufficient to determine the effects of the technology on health outcomes.
Benign Thyroid Tumors

For individuals with benign thyroid tumors who receive RFA, the evidence includes RCTs, prospective studies, case series, and systematic reviews of these studies. Relevant outcomes are symptoms, change in disease status, quality of life, medication use, and treatment-related morbidity. A systematic review that included 4 RCTs and 5 observational studies found significant reductions in nodule size and withdrawal from methimazole following treatment with RFA when compared to a variety of other local treatments. Reports of complications vary. The most frequent major complication from a large multicenter series of specialty centers was voice change. The evidence is insufficient to determine the effects of the technology on health outcomes.

Miscellaneous Solid Tumors

For individuals with miscellaneous tumors (eg, head and neck, thyroid cancer, pancreas) who receive RFA, the evidence includes a few case series and retrospective comparative studies. Relevant outcomes are overall survival, change in disease status, quality of life, and treatment-related morbidity. There is a limited evidence base for these tumor types. Reporting on outcomes or comparisons with other treatments is limited. These studies do not permit conclusions on the health benefits of RFA. The evidence is insufficient to determine the impact of the technology on health outcomes.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>NCT01051037</td>
<td>Phase II Study Evaluating Safety and Efficacy of Stereotactic Body Radiotherapy and Radiofrequency</td>
<td>17</td>
<td>Dec 2017 (ongoing)</td>
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<tr>
<td>NCT No.</td>
<td>Trial Name</td>
<td>Planned Enrollment</td>
<td>Completion Date</td>
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</tr>
<tr>
<td></td>
<td>Ablation for Medically Inoperable and Recurrent Lung Tumors Near Central Airways</td>
<td></td>
<td></td>
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<tr>
<td>Unpublished</td>
<td>Radiofrequency Ablation in Resectable Colorectal Lung Metastasis: A Phase-II Clinical Trial</td>
<td>70</td>
<td>Aug 2018 (completed)</td>
</tr>
</tbody>
</table>

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 2 physician specialty societies (4 reviewers) and 2 academic medical centers (4 reviewers) while this policy was under review in 2010. The input was similar to that in 2009, except support for use of radiofrequency ablation (RFA) to treat lung tumors was declined (only 1 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 could substantially worsen kidney function or when the patient is not considered a surgical candidate.

2009 Input

In response to requests, input was received from 1 physician specialty society (4 reviews) and from 2 academic medical centers (3 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 patients, 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 patients. With the exception of 1 disagreement and 1 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

American College of Chest Physicians

The American College of Chest Physicians guidelines (2013) on the treatment of stage I and II non-small-cell lung cancer (NSCLC) have indicated radiofrequency ablation (RFA) has been used effectively in clinical stage I NSCLC. 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. These 2012 consensus guidelines indicated RFA is an alternative treatment option in patients who are not surgical candidates due to severe medical comorbidity.

National Comprehensive Cancer Network

National Comprehensive Cancer Network (NCCN) practice guidelines for the treatment of NSCLC (v.6.2018) state, “Resection is the preferred local treatment modality (other modalities include radiofrequency ablation, cryotherapy and SABR [stereotactic ablative radiotherapy]).”

NCCN guidelines for thyroid carcinoma (v.2018) indicate that local therapies such as RFA may be considered for locoregional recurrence of thyroid carcinoma-papillary carcinoma.

NCCN guidelines (v.2018) for renal cancer indicate that ablative techniques such as RFA “can be considered for selected patients with clinical stage T1 renal disease.” The guidelines note that ablative techniques are associated with higher rates of local recurrence than traditional surgery.

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (NICE) guidance (2004) on osteoid osteoma has indicated that “current evidence on the safety and efficacy of computed
tomography (CT)-guided thermocoagulation of osteoid osteoma appears adequate to support its use...\textsuperscript{68}

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.”\textsuperscript{69}

NICE guidance (2010) on RFA for primary and secondary lung cancers has stated: “[C]urrent evidence on the efficacy of percutaneous radiofrequency ablation (RFA) ... is adequate in terms of tumor control.”\textsuperscript{70} 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.

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....”\textsuperscript{71}

**Medicare National Coverage**

There is no national coverage determination.

**Regulatory Status**

The U.S. Food and Drug Administration (FDA) issued a statement in September 2008 concerning the regulatory status of RFA. 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. 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. 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**
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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 clarification. CPT codes 47380 and 47382 removed from policy; these procedures are...
<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>03/11/14</td>
<td>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.</td>
</tr>
<tr>
<td>09/03/14</td>
<td>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.</td>
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<tr>
<td>12/17/14</td>
<td>Annual Review. Policy updated with literature review through September 18, 2014; policy statements unchanged. References 13, 18-19 and 47 added.</td>
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<tr>
<td>11/10/15</td>
<td>Annual Review. Policy updated with literature review through July 28, 2015; references 4, 48, and 56 added; other references deleted. Policy statements unchanged.</td>
</tr>
<tr>
<td>11/01/16</td>
<td>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.</td>
</tr>
<tr>
<td>11/24/16</td>
<td>Updated Related Policies, removed 8.01.528 as it was archived.</td>
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</table>

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**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.
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  • Qualified interpreters
  • Information written in other languages

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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room S09F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost.
Call 800-722-1471 (TTY: 800-842-5357).

اللغة الإنجليزية (Arabic):
يحيى هذا الإشعار معلومات هامة. قد يحيى هذا الإشعار معلومات مهمة بخصوص طلبي أو
العملية التي تتعلق الحصول عليها من خلال Premera Blue Cross. هذه المعلومة تتعلق في هذا الإشعار. قد تحتاج لإجازة في تأدية مهنة للحصول على معلومات الصحة أو المساعدة في دفع التكاليف. يحق لك الحصول على هذه المعلومات والمساعدة بكل تكلفة دون تكلفة أخرى. تصل
800-722-1471 (TTY: 800-842-5357) للمزيد.

中文 (Chinese):
本通知有重要的讯息。本通知可能有關於您透過 Premera Blue Cross 提交的申請或保險的重要訊息。本通知內可能有重要日期。您可能需要在截止日期之前採取行動。以保留您的健康保險或費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話 800-722-1471 (TTY: 800-842-5357).

Oromo (Cushite):

Deutsche (German):

Italiano (Italian):
Este aviso podrá contener información importante a respe...