Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors

Policy # 00175
Original Effective Date: 08/24/2005
Current Effective Date: 07/18/2019

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Stereotactic Radiosurgery and Stereotactic Body Radiotherapy is addressed separately in medical policy 00045.

Note: The use of Radiofrequency Ablation (RFA) of Primary or Metastatic Liver Tumors is addressed separately in medical policy 00182.

Note: Cryosurgical Ablation of Primary or Metastatic Liver Tumors is addressed separately in medical policy 00220.

When Services Are Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:
- Benefits are available in the member’s contract/certificate, and
- Medical necessity criteria and guidelines are met.

Osteolytic Bone Metastases
Based on review of available data, the Company may consider radiofrequency ablation (RFA) to palliate pain in patients with osteolytic bone metastases who have failed or are poor candidates for standard treatments such as radiation or opioids to be eligible for coverage.**

Localized Renal Cell Carcinoma
Based on review of available data, the Company may consider RFA to treat localized renal cell carcinoma (RCC) that is no more than 4 cm in size to be eligible for coverage.**

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Patient Selection Criteria
Coverage eligibility for RFA to treat localized renal cell carcinoma (RCC) that is no more than 4 cm in size will be considered when EITHER of the following is met:

- In order to preserve kidney function in patients with significantly impaired renal function (i.e., the patient has one kidney or renal insufficiency defined by a glomerular filtration rate [GFR] of less than 60 mL/min/m\(^2\)); AND
- The standard surgical approach (i.e., resection of renal tissue) is likely to substantially worsen kidney function; OR
- Patient is not considered a surgical candidate.

**Isolated Peripheral Non-Small Cell Lung Cancer Lesion**
Based on review of available data, the Company may consider RFA to treat an isolated peripheral non-small cell lung cancer (NSCLC) lesion that is no more than 3 cm in size to be **eligible for coverage.**

Patient Selection Criteria
Coverage eligibility for RFA to treat an isolated peripheral NSCLC lesion that is no more than 3 cm in size will be considered when ALL of the following criteria are met:

- Surgical resection or radiation treatment with curative intent is considered appropriate based on stage of disease, however, medical co-morbidity renders the individual unfit for those interventions; AND
- Tumor is located at least 1 cm from the trachea, main bronchi, esophagus, aorta, aortic arch branches, pulmonary artery and the heart.

**Malignant Non-Pulmonary Tumor(s) Metastatic to the Lung**
Based on review of available data, the Company may consider RFA to treat malignant non-pulmonary tumor(s) metastatic to the lung that are no more than 3 cm in size to be **eligible for coverage.**

Patient Selection Criteria
Coverage eligibility for RFA to treat malignant non-pulmonary tumor(s) metastatic to the lung that are no more than 3 cm in size when ALL of the following criteria are met:
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- In order to preserve lung function when surgical resection or radiation treatment is likely to substantially worsen pulmonary status; OR
- The patient is not considered a surgical candidate; AND
- There is no evidence of extrapulmonary metastases; and the tumor is located at least 1 cm from the trachea, main bronchi, esophagus, aorta, aortic arch branches, pulmonary artery and the heart; and

When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers radiofrequency ablation to be investigational as a technique for ablation of:

- Breast tumors;
- Lung cancer not meeting the criteria above;
- Renal cell cancer not meeting criteria above;
- Osteoid osteomas that can be managed with medical treatment;
- Painful bony metastases as initial treatment; and
- All other tumors outside the liver including, but not limited to, the head and neck, thyroid, adrenal gland, ovary, and pelvic/abdominal metastases of unspecified origin.

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.

Background/Overview
Osteolytic Bone Metastases
After lung and liver, bone is the third most common metastatic site and is relatively frequent 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 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 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 an 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 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- 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 the 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
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head and postoperative pathologic fracture. In addition, surgical excision leads to a lengthier 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 I primary non-small-cell lung cancer (NSCLC; stage I includes Ia [T1N0M0] and Ib [T2N0M0]). Approximately 20% of patients present with stage I 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 I 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 I patients, with 5-year overall survival rates ranging from 77% for small T1 tumors to 35% for large T2 tumors. Untreated, stage I 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- to 3-year local control rates of stage I 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 also is 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 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 different lesions in different anatomic sites. These anatomic sites include, but are not limited to, breast and 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
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offered. The safety and efficacy of RFA have been investigated as an option for palliative treatment in these situations.

**Radiofrequency Ablation**

RFA was initially developed to treat inoperable tumors of the liver (see medical policy 00182). Recently, studies have reported on the use of RFA to treat other tumors. For some of these, RFA is being investigated as an alternative to surgery for operable tumors. Well-established local or systemic treatment alternatives are available for each of these malignancies. The hypothesized advantages of RFA for these cancers include improved local control and those common to any minimally invasive procedure (eg, preserving normal organ tissue, decreasing morbidity, decreasing length of hospitalization).

Goals of RFA may include (1) controlling local tumor growth and preventing recurrence; (2) palliating symptoms; and (3) extending survival duration for patients with certain tumors. The effective volume of RFA depends on the frequency and duration of applied current, local tissue characteristics, and probe configuration (eg, single vs multiple tips). RFA can be performed as an open surgical procedure, laparoscopically or percutaneously, with ultrasound or computed tomography guidance.

Potential complications associated with RFA include those caused by heat damage to normal tissue adjacent to the tumor (eg, intestinal damage during RFA of kidney), structural damage along the probe track (eg, pneumothorax as a consequence of procedures on the lung), and secondary tumors (if cells seed during probe removal).

**FDA or Other Governmental Regulatory Approval**

**U.S. Food and Drug Administration (FDA)**

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 non-resectable 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
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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.

Rationale/Source
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- 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.

Bone Tumors
For individuals who have painful osteolytic bone metastases who have failed or are poor candidates for standard treatments who receive RFA, the evidence includes case series. Relevant outcomes are symptoms, change in disease status, quality of life, medication use, and treatment-related morbidity. Case series have shown clinically significant pain relief and reduction in opioid use following treatment of painful osteolytic metastases. The population is comprised of patients with few or no treatment options, for whom short-term pain relief is an appropriate clinical outcome. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

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

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Localized Renal Cell Carcinoma
For individuals who have localized renal cell carcinoma that is no more than 4 cm in size who receive RFA, the evidence includes a randomized controlled trial (RCT), numerous observational studies, and systematic reviews of these studies. 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 I (≤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.

Clinical input obtained in 2010 supported use of RFA for localized renal cell carcinoma that is no more than 4 cm in size when preservation of kidney function is necessary, and a standard surgical approach is likely to worsen kidney function substantially or when the patient is not considered a surgical candidate. Thus, absent other treatment options, RFA for small renal cell tumors may be considered medically necessary.

Inoperable Primary Pulmonary and Non-pulmonary Tumors
For individuals who have inoperable primary pulmonary tumors or non-pulmonary tumors metastatic to the lung who receive RFA, the evidence includes prospective 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 in size, RFA can lead to a complete response in as many as 88% of patients for at least 1 year. Two-year survival rates have been reported to range from 41% to 75% in case series, with 5-year survival rates of 20% to 27%. In general, the evidence suggests that RFA results in adequate survival and tumor control in patients who are not surgical candidates, with low morbidity rates. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.
Breast Tumors
For individuals who have breast tumors who receive RFA, the evidence includes observational studies and systematic reviews of these studies. 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 post-ablation 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 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, 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 with a variety of local treatment. Reports of complications vary. The most frequent major complication in 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 who have 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.
Supplemental Information

Clinical Input 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. Input was similar to that received in 2009, except support for the use of radio frequency 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 would likely 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
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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 for patients who are not surgical candidates due to severe medical comorbidity.

**National Comprehensive Cancer Network**
National Comprehensive Cancer Network (NCCN) 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 lesions.” 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 indicated that “current evidence on the safety and efficacy of computed tomography (CT)-guided thermocoagulation of osteoid osteoma appears adequate to support its use....”

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.”

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.” 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.
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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…”

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.

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

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<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<td>NCT01051037</td>
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<td>17</td>
<td>Dec 2017 (ongoing)</td>
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<td>Radiofrequency Ablation in Resectable Colorectal Lung Metastasis: A Phase-II Clinical Trial</td>
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<td>Aug 2018 (completed)</td>
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NCT: national clinical trial.

References
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07/13/2005 Medical Director review
07/19/2005 Medical Policy Committee review
08/24/2005 Managed Care Advisory Council approval
07/07/2006 Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
08/08/2006 Medical Director review
08/09/2006 Medical Policy Committee approval.
07/10/2007 Medical Director review
07/02/2008 Medical Director review
07/16/2008 Medical Policy Committee approval. Coverage eligibility unchanged.
07/02/2009 Medical Director review
07/22/2009 Medical Policy Committee approval. Coverage statement added to indicate that use of radiofrequency ablation as treatment of osteoid osteomas that cannot be managed successfully with medical treatment may be considered eligible for coverage. Coverage statement added that treatment of localized renal cell carcinoma no more than 4cm in size may be considered eligible for coverage when specific criteria are met. Added that radiofrequency ablation for the treatment of osteoid osteomas that can be managed with medical treatment is considered to be investigational.
08/05/2010 Medical Policy Committee review
08/18/2010 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/04/2011 Medical Policy Committee review
08/02/2012 Medical Policy Committee review
08/15/2012 Medical Policy Implementation Committee approval. Added options for primary and metastatic pulmonary tumors to be eligible for coverage with criteria.
12/12/2013 Medical Policy Committee review
12/18/2013 Medical Policy Implementation Committee approval. Reformatted investigational statement and added thyroid as investigational.
06/25/2015 Medical Policy Committee review
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07/15/2015 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/30/2016 Medical Policy Committee review
07/20/2016 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017 Coding update: Removing ICD-9 Diagnosis codes
07/06/2017 Medical Policy Committee review
07/19/2017 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2018 Coding update
07/05/2018 Medical Policy Committee review
08/31/2018 Coding update
07/03/2019 Medical Policy Committee review
07/18/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 07/2020

Coding
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*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or

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Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors

Policy # 00175  
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3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;

B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and

C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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