Protocol

Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors

(70195)

Medical Benefit		Effective Date: 01/01/14	Next Review Date: 11/20
Preauthorization	No	**Review Dates:** 11/07, 11/08, 09/09, 09/10, 09/11, 09/12, 09/13, 07/14, 07/15, 11/15, 11/16, 11/17, 11/18, 11/19	

Preauthorization is not required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: • With painful osteolytic bone metastases who have failed or are poor candidates for standard treatments	Interventions of interest are: • Radiofrequency ablation	Comparators of interest are: • Medical management • Radiotherapy	Relevant outcomes include: • Symptoms • Change in disease status • Quality of life • Medication use • Treatment-related morbidity
Individuals: • With painful osteoid osteomas	Interventions of interest are: • Radiofrequency ablation	Comparators of interest are: • Medical management • Surgical excision • Core drill excision • Laser photocoagulation	Relevant outcomes include: • Symptoms • Change in disease status • Quality of life • Medication use • Treatment-related morbidity
Individuals: • With localized renal cell carcinoma no more than four cm in size	Interventions of interest are: • Radiofrequency ablation	Comparators of interest are: • Surgical excision	Relevant outcomes include: • Overall survival • Change in disease status • Quality of life • Treatment-related morbidity
Individuals: • With inoperable primary pulmonary tumors or nonpulmonary tumors metastatic to the lung	Interventions of interest are: • Radiofrequency ablation	Comparators of interest are: • Radiotherapy	Relevant outcomes include: • Overall survival • Change in disease status • Quality of life • Treatment-related morbidity
Individuals: • With breast tumors	Interventions of interest are: • Radiofrequency ablation	Comparators of interest are: • Radiotherapy • Surgical excision	Relevant outcomes include: • Overall survival • Change in disease status • Quality of life • Treatment-related morbidity
Individuals: • With benign thyroid tumors	Interventions of interest are: • Radiofrequency ablation	Comparators of interest are: • Radiotherapy • Surgical excision	Relevant outcomes include: • Symptoms • Change in disease status • Quality of life • Medication use • Treatment-related morbidity

Populations	Interventions	Comparators	Outcomes
Individuals: • With miscellaneous solid tumors (e.g., head and neck, thyroid cancer, pancreas)	Interventions of interest are: • Radiofrequency ablation	Comparators of interest are: • Radiotherapy • Surgical excision	Relevant outcomes include: • Overall survival • Change in disease status • Quality of life • Treatment-related morbidity

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 a local recurrence, it occurs at the edge and can sometimes be retreated. RFA may be performed percutaneously, laparoscopically, or as an open procedure.

SUMMARY OF EVIDENCE

BONE TUMORS

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

LOCALIZED RENAL CELL CARCINOMA

For individuals who have localized renal cell carcinoma that is no more than 4 cm in size who receive RFA, the evidence includes a randomized controlled trial (RCT), numerous observational studies, and systematic reviews of these studies. Relevant outcomes are overall survival (OS), change in disease status, QOL, and treatment-related morbidity. A recent meta-analysis that included only an RCT and cohort studies found that RFA was as effective as nephrectomy for small renal tumors, with a reduction in complications. Another recent meta-analysis found that partial nephrectomy 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. 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 NONPULMONARY TUMORS

For individuals who have inoperable primary pulmonary tumors or nonpulmonary tumors metastatic to the lung who receive RFA, the evidence includes prospective observational studies and systematic reviews of these studies. Relevant outcomes are OS, change in disease status, QOL, and treatment-related morbidity. A multicenter study found that for tumors less than 3.5 cm in size, RFA can lead to a complete response in as many as 88% of patients for at least 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 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 OS, change in disease status, QOL, and treatment-related morbidity. Evidence has reported varied and incomplete ablation rates with concerns about postablation tumor cell viability. Long-term improvements in health outcomes have not been demonstrated. Additionally, available studies do not permit comparisons with conventional breast-conserving procedures. Further studies, with long-term follow-up, should focus on whether RFA of the breast for small tumors can provide local control and survival rates compared with conventional breast-conserving treatment. The evidence is insufficient to determine the effects of the technology on health outcomes.

BENIGN THYROID TUMORS

For individuals who have benign thyroid tumors who receive RFA, the evidence includes RCTs, prospective studies, case series, and systematic reviews of these studies. Relevant outcomes are symptoms, change in disease status, QOL, medication use, and treatment-related morbidity. A systematic review that included four RCTs and five 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 (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. Relevant outcomes are OS, change in disease status, QOL, and treatment-related morbidity. There is a limited evidence base for these tumor types. Reporting on outcomes or comparisons with other treatments is limited. These studies do not permit conclusions on the health benefits of RFA. The evidence is insufficient to determine the impact of technology on health outcomes.

POLICY

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

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

Radiofrequency ablation may be considered **medically necessary** to treat localized renal cell carcinoma that is no more than four 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 (i.e., the patient has one kidney or renal insufficiency defined by a glomerular filtration rate of less than 60 mL/min/m^2) AND
- When the standard surgical approach (i.e., resection of renal tissue) is likely to worsen existing kidney function substantially; OR
- When 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 three 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 one cm from the trachea, main bronchi, esophagus, aorta, aortic arch branches, pulmonary 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 three 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 extrapulmonary metastases; AND the tumor is located at least one cm from the trachea, main bronchi, esophagus, aorta, aortic arch branches, pulmonary artery and the heart.

(See the Policy Guidelines for additional criteria.)

Radiofrequency ablation is considered **investigational** as a technique for ablation of:

- breast tumors;
- lung cancer not meeting the criteria above;
- renal cell cancer not meeting the criteria above;
- osteoid osteomas that can be managed with medical treatment;
- painful bony metastases as initial treatment; and
- all other tumors outside the liver including, but not limited to, the head and neck, thyroid, pancreas, adrenal gland, ovary, and pelvic/abdominal metastases of unspecified origin.

POLICY GUIDELINES

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

- No more than three 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

RADIOFREQUENCY ABLATION

RFA was initially developed to treat inoperable tumors of the liver (see the Radiofrequency Ablation of Primary or Metastatic Liver Tumors Protocol). 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 (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 (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).

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) issued a statement in September 2008, concerning the regulatory status of RFA. The FDA has cleared RFA devices for the general indication of soft tissue cutting, coagulation, and ablation by thermal coagulation necrosis. Under this general indication, RFA can be used to ablate tumors, including lung tumors. Some RFA devices have been cleared for additional specific treatment indications, including partial or complete ablation of nonresectable liver lesions and palliation of pain associated with metastatic lesions involving bone. The FDA has not cleared any RFA devices for the specific treatment indication of partial or complete ablation of lung tumors, citing lack of sufficient clinical data to establish safety and effectiveness for this purpose. The FDA has received reports of death and serious injuries associated with the use of RFA devices in the treatment of lung tumors.

RELATED PROTOCOLS

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

Radiofrequency Ablation of Primary or Metastatic Liver Tumors

Stereotactic Radiosurgery and Stereotactic Body Radiotherapy

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

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We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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