Medical Coverage Policy | Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors

Blue Cross Blue Shield of Rhode Island

EFFECTIVE DATE: 6|1|2010
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OVERVIEW

In radiofrequency ablation (RFA), a probe is inserted into the center of a tumor and the noninsulated electrodes, which are shaped like prongs, are projected into the tumor; heat is then generated locally by a high-frequency, alternating current that flows from the electrodes. The local 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, in some cases, may be retreated. RFA may be performed percutaneously, laparoscopically, or as an open procedure.

MEDICAL CRITERIA

BlueCHiP for Medicare and Commercial

RFA 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:

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

RFA 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:

- In order to preserve lung function when surgical resection or radiation treatment is likely to substantially worsen pulmonary status;
- The patient is not considered a surgical candidate;
- There is no evidence of extrapulmonary metastases;
- The tumor is located at least 1 cm from the trachea, main bronchi, esophagus, aorta, aortic arch branches, pulmonary artery and the heart.

RFA as a palliative treatment for pain is covered when the following criteria is met:

- In patients with osteolytic bone metastases who have failed or are poor candidates for standard treatments such as radiation or opioids.

RFA as a treatment for osteoid osteomas is covered when the following criteria is met:

- The osteoid osteoma cannot be managed successfully with medical treatment.

PRIOR AUTHORIZATION

Prior authorization is required for BlueCHiP for Medicare and recommended for Commercial products.

POLICY STATEMENT

Radiofrequency ablation of tumors located in the lung or an isolated peripheral non-small-cell lung cancer lesion or to palliate pain in patients with osteolytic bone metasteses or to treat osteoid osteomas is covered for patients who meet the medical criteria listed above; all other indications are considered not medically necessary due to lack of peer-reviewed literature which supports improved health outcomes. RFA is considered not medically necessary as a technique for ablation of the following:

- Breast tumors
- Lung 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, adrenal gland, ovary and pelvic/abdominal metastases of unspecified origin

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for the applicable surgery services benefits/coverage.

BACKGROUND

RFA is being evaluated to treat various tumors, including inoperable tumors, or to treat patients ineligible for surgery due to age, presence of comorbidities, or poor general health. 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 (CT) 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), or secondary tumors if cells seed during probe removal.

RFA was initially developed to treat inoperable tumors of the liver. Recently, reports have been published on use of RFA to treat renal cell carcinoma's, breast tumors, pulmonary cancers (including primary and metastatic lung tumors), bone, and 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).

Breast Tumors

There has been a trend in the treatment of small breast cancers from total mastectomy toward increasingly 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 killing, and local recurrence. Additionally, RFA can cause burning of the skin or damage to muscle, possibly limiting use in patients with tumors near the skin or chest wall.

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, and 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.

Osteoid Osteomas

Osteomas are the most common type of 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 (NSAIDs). The natural history of the osteoid osteoma varies based on its location, and although they rarely exceed 1.5 cm, 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 options include medical management with NSAIDs, surgical excision (wide/en bloc excision or curetting), or the use of CT- 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. Complete surgical excision has several disadvantages. A substantial incision may be necessary and removal of a considerable amount of bone (especially in the neck of the femur) increases the need for bone grafting and/or 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, and patients may immediately walk on the treated extremity and return to daily activities as soon as 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.

Palliation for 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. 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 such as 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 palliating pain from bone metastases.

Case series have included a limited number of cases. However, the patient populations comprised patients with limited or no treatment options, for whom short-term pain relief is an appropriate outcome. Therefore, the use of RFA as palliative therapy in patients with painful metastatic bone lesions may be considered medically necessary. There are no randomized trials for this indication, however, uncontrolled studies have demonstrated RFA can provide adequate pain relief with minimal complications. Therefore, the use of RFA for the treatment of osteoid osteomas that cannot be successfully treated with medical treatment may be considered medically necessary

Pulmonary Tumors
Surgery is the current treatment of choice in patients with stage 1 primary NSCLC, (non-small-cell lung cancer), (stage 1 includes 1a: T1N0M0 and 1b: T2N0M0). Only 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 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% of patients. Large differences in survival outcome are observed after surgery in stage 1 patients, with 5-year overall survival (OS) rates, ranging from 77% for small T1 tumors to 35% for large T2 tumors. Untreated, stage 1 NSCLC has a 5-year OS rate of 6% to 14%.5

Patients with early stage NSCLC who are not surgical candidates may be candidates for radiation treatment with curative intent. In the two largest 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. While available studies are limited by study design, accumulating evidence from case series suggests that RFA may be a treatment option in selected patients with primary, NSCLC and metastatic pulmonary tumors. Although complications have been reported with the use of RFA in the lung, evidence suggests RFA may have survival rates and have rates of procedure-related complications and mortality similar to surgery. Surgical resection remains the treatment of choice, but in patients unable to tolerate surgery due to medical comorbidities, RFA may be considered a treatment option.

Stereotactic radiotherapy (SRT) has gained more widespread use, as it is a high-precision mode of therapy that allows for delivery of very high doses of radiation. Two- to three year local control rates of stage 1 NSCLC with SRT have ranged from 80% to 95%. Many reports on outcomes with SRT have been in patients unfit to undergo surgery, introducing a large selection bias compared with that in surgery. However, one study that reported on nearly 100 patients who refused surgery (versus being deemed unfit) had a 5-year OS rate of 71% with SRT to treat stage 1 NSCLC, a rate that is at least equivalent to surgical outcome.

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.

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

CODING

Blue CHiP for Medicare and Commercial
The following codes are considered medically necessary:
20982
32998

RELATED POLICIES

None

PUBLISHED

Provider Update, May 2015
Provider Update, Aug 2014
Provider Update, Sep 2012
Provider Update, Sep 2011
Provider Update, Aug 2010

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