



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

Subject Radiofrequency Ablation (RFA) of Pulmonary Tumors

Effective Date 2/15/2011
Next Review Date 2/15/2013
Coverage Policy Number 0440

Table of Contents

Coverage Policy	1
General Background	1
Coding/Billing Information	4
References	4
Policy History	8

Hyperlink to Related Coverage Policies

Photodynamic Therapy for Cancer
Stereotactic Radiosurgery (SRS) and
Stereotactic Body Radiation Therapy (SBRT)

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Coverage Policy

CIGNA covers radiofrequency ablation (RFA) as medically necessary for the treatment of lung masses in individuals with non-small cell lung cancer (NSCLC) or lung metastases who are not appropriate candidates for surgical intervention.

General Background

Cancers that begin in the lungs are divided into two major types, non-small cell lung cancer (NSCLC) and small cell lung cancer (SCLC). Each type of lung cancer grows and spreads in different ways and is treated differently. NSCLC is more common than SCLC, and it generally grows and spreads more slowly (National Cancer Institute [NCI], 2011; NCI, 2009; NCI, 2007).

Treatment of lung cancer depends on a number of factors, including the type of lung cancer (i.e., NSCLC or SCLC) the size, location, and extent of the tumor and the general health of the patient. Many different treatments and combinations of treatments may be used to control lung cancer, and/or to improve quality of life by reducing symptoms. Treatment options for lung cancer include surgery, chemotherapy, radiation therapy, targeted therapy, or a combination of treatments (NCI, 2007).

Surgical resection is generally considered the treatment of choice for early-stage NSCLC. Patients with NSCLC are frequently poor candidates for surgical resection due to comorbidities (e.g., chronic obstructive disease, cardiovascular disease or limited pulmonary function). NSCLC can recur even after surgical resection. Systemic

chemotherapy and radiation therapy have improved survival outcomes in patients who have inoperable or nonresectable pulmonary tumors (Lencioni, et al., 2004).

An alternative to surgical removal of pulmonary tumors is eliminating the tumor cells using heat, while sparing nearby healthy lung tissue. The technique, called radiofrequency ablation (RFA), is a minimally invasive procedure performed by interventional radiologists. RFA has been used for the treatment of a variety of neoplasms, including primary and secondary hepatic malignancies, and tumors located in the kidney, bone, breast, and brain. The potential benefits of RFA include decreased morbidity compared to surgical removal, as well as treatment for patients who are not surgical candidates due to comorbidities, age, or extent of disease. Guided primarily by computed tomography (CT) scanning, a small needle electrode is inserted through the skin and directly into the tumor tissue. Radiofrequency energy consisting of an alternating electrical current in the frequency of radio waves is passed through the electrode. The energy causes the tissues around the needle electrode to heat up, killing nearby cancer cells. At the same time, heat from radiofrequency energy closes small blood vessels and lessens the risk of bleeding. RFA generally causes little discomfort. It is typically done as an outpatient procedure that does not call for general anesthesia. RFA may not be practical if the tumor being treated is close to a critical organ such as the heart, central airways, or blood vessels. Large lung tumors and those that are difficult to reach may require repeated RFA treatments. The most commonly reported complications of RFA are pneumothorax and bleeding (Arenberg and Pickens, 2010; Lee, et al., 2004).

U.S. Food and Drug Administration (FDA)

In December 2007, the FDA issued a Public Health Notification to healthcare practitioners relating to reports of deaths associated with the use of RFA devices during lung tumor ablation (FDA, 2007). In September 2008, the FDA issued an updated Public Health Notification to clarify the regulatory status of RFA devices used to treat lung tumors, the regulatory basis for FDA's clearance of these devices for the indication of general soft tissue ablation, and the specific health concerns related to the specific use of RFA to treat lung tumors (FDA, 2008). The FDA Public Health Notification states:

“Regulatory status: FDA has cleared RF ablation devices for the general indication of soft tissue cutting, coagulation, and ablation by thermal coagulation necrosis. This clearance was based only on bench testing data or animal testing performance data. Under this general indication, RF ablation can be used as a tool to ablate tumors, including lung tumors. Some RF ablation 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. In order for an ablation device to obtain clearance for specific treatment indications, clinical data are necessary to justify the indications by showing that the device, when used on a well-defined target population, consistently achieves the desired treatment effect. FDA has not cleared any RF ablation devices for the specific treatment indication of partial or complete ablation of lung tumors. Manufacturers of RF ablation devices cannot legally market them for this treatment indication until they have presented to FDA clinical data sufficient to establish safety and effectiveness for this purpose. Manufacturers have asked that they be allowed to provide training for clinicians related to this ablation of pulmonary tumor use. FDA cannot permit manufacturer-sponsored training for a specific indication that has not been cleared. This does not apply to training that may be available from other sources.

Public health concerns: FDA has received reports of death and serious injuries associated with the use of RF ablation devices in treatment of lung tumors. Since we have not reviewed any pre-market clinical data in support of this specific treatment use, we do not know the actual adverse event rate. Therefore, we cannot say if these deaths or injuries are occurring more frequently than with other forms of treatment for lung tumors. These adverse events could be related to a number of factors, including patient selection and management, technical use of the RF device, post procedural treatments, and management of complications.”

The FDA states that to get the most recent information on adverse events due to lung tumor ablation check the MAUDE database.

Literature Review

Evidence in the published peer-reviewed literature supports the use of RFA for the treatment of lung masses in individuals with non-small cell lung cancer (NSCLC) or lung metastases. However, there are a limited number of published studies evaluating long-term outcomes after RFA of primary and secondary pulmonary tumors. Continued evaluation is needed to determine the impact on long-term outcomes and to compare RFA to standard treatments. In general, results of the studies to date indicate that RFA is an effective and relatively safe

alternative for individuals with non-small cell lung cancer (NSCLC) or lung metastases who are not appropriate candidates for surgical intervention. RFA has been reported to be more effective for small, early-stage pulmonary tumors (Lencioni, et al., 2008; Simon, et al., 2007; Rossi, et al., 2006; Ambrogi, et al., 2006; Kishi, et al., 2006; Dupuy, et al., 2006; Fernando, et al., 2005; Bojarski, et al., 2005; Belfiore, et al., 2004; Akeboshi, et al., 2004; Yasui, et al., 2004; Lee, et al., 2004; Suh, et al., 2003; Herrera, et al., 2003).

Additional small case studies by Dupuy et al. (2000), Schafer et al. (2003), Jin et al. (2004), King et al. (2004), Hataji et al. (2005), Nguyen et al. (2005), Pennathur et al. (2007), Hiraki et al. (2007), and Cariati et al. (2007) focused on tumor response to RFA and technical feasibility.

In a review of lung cancer and RFA, Rose et al. (2006) reported on a meta-analysis of 15 published case series on RFA of lung tumors that included more than 600 patients. All patients were either not candidates for surgical treatment or had refused surgery. Half of the patients had primary NSCLC and half had metastases. The authors stated that a significant minority of patients may benefit from RFA. When potential cure is the therapeutic goal, RFA is recommended in patients who are not amenable to surgery with stage I NSCLC and patients with a limited number of small, slow-growing metastases restricted to the lungs. The authors stated that complete tumor ablation is achieved in patients with lesions no larger than 3 cm in diameter. RFA may be used in patients with larger tumors, although they may require subsequent RFA sessions. Preliminary survival data is reported as encouraging, but definitive evidence supporting the use of RFA to prolong survival is needed.

In an updated interventional guidance on percutaneous RFA for primary and secondary lung cancers, the National Institute for Clinical Excellence (United Kingdom) states that "Current evidence on the efficacy of percutaneous radiofrequency ablation (RFA) for primary or secondary lung cancers is adequate in terms of tumor control. There is a small incidence of complications, specifically pneumothorax, which may have serious implications for these patients with already compromised respiratory reserve. This procedure may be used provided that normal arrangements are in place for clinical governance, consent and audit. Patient selection for percutaneous RFA for primary or secondary lung cancers should be carried out by a multidisciplinary team, which will usually include a thoracic surgeon, an oncologist and a radiologist. This procedure should only be carried out by radiologists who regularly undertake image guided interventional procedures. NICE encourages further research into this procedure. Research studies should include a clear description of case mix and lesion size, and report long-term survival. radiotherapy, chemotherapy or a combination of these treatments. If the tumor protrudes into major airways, bronchoscopic treatments including diathermy, laser therapy, cryotherapy, brachytherapy and photodynamic therapy may be used" (NICE, 2010).

Professional Societies/Organizations

The 2011 National Comprehensive Cancer Network (NCCN) Practice Guideline on NSCLC states RFA may be an option for node-negative patients who either refuse surgery or cannot tolerate surgery because of poor performance status, significant cardiovascular risk, poor pulmonary function, and/or comorbidities. Optimal candidates for RFA include patients with an isolated peripheral lesion less than 3 cm. RFA can be used for previously irradiated tissue for palliation (NCCN, 2011).

The National Cancer Institute (NCI) NSCLC Physician Data Query (PDQ[®]) treatment option overview for NSCLC does not mention RFA. The NCI states, "Current areas under evaluation include combining local treatment (surgery, regional treatment (radiation therapy), systemic treatments (chemotherapy, immunotherapy, and targeted agents), developing effective systemic therapy" (NCI, 2011).

In the American Cancer Society (ACS) overview on how NSCLC is treated, RFA is mentioned in other local treatments stating that, RFA is being studied for small lung tumors that are near the outer edge of the lungs, especially in people who can't have or don't want surgery. Major complications are uncommon, but they can include the partial collapse of a lung (which often resolves on its own) or bleeding into the lung (ACS, 2010).

Summary

The use of radiofrequency ablation (RFA) is an established technique for treatment of focal malignancies in the liver and bone. Limited short-term results published in the peer-reviewed literature suggest that RFA may be a palliative treatment option for patients with early-stage NSCLC who have exhausted, or have contraindications to, conventional treatment options. RFA has been shown to be technically feasible in patients with small, early-stage pulmonary tumors. It may be used as complementary treatment reaching cancer cells that are resistant to chemotherapy or radiation therapy. Reports of patient deaths associated with lung tumor ablation using RFA

devices emphasize the importance of considering the potential risks versus benefits of this therapy. There are limited published studies on the long-term outcomes after RFA of primary and secondary pulmonary tumors. Continued evaluation is needed to determine long-term outcomes and to compare RFA to standard treatments.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

CPT®* Codes	Description
32998	Ablation therapy for reduction or eradication of one or more pulmonary tumor(s) including pleura or chest wall when involved by tumor extension, percutaneous, radiofrequency, unilateral

ICD-9-CM Diagnosis Codes	Description
162.3	Malignant neoplasm of upper lobe, bronchus, or lung
162.4	Malignant neoplasm of middle lobe, bronchus, or lung
162.5	Malignant neoplasm of lower lobe, bronchus, or lung
162.8	Malignant neoplasm of other parts of bronchus or lung
162.9	Malignant neoplasm of bronchus and lung, unspecified site
209.21	Malignant carcinoid tumor of bronchus and lung
231.2	Carcinoma in situ of bronchus and lung

*Current Procedural Terminology (CPT®) ©2010 American Medical Association: Chicago, IL.

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Policy History

<u>Pre-Merger Organizations</u>	<u>Last Review Date</u>	<u>Policy Number</u>	<u>Title</u>
CIGNA HealthCare	2/15/2008	0440	Radiofrequency Ablation (RFA) of Pulmonary Tumors

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