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

EFFECTIVE DATE: 03|01|2023
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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

Medicare Advantage Plans and Commercial Products

RFA to treat an isolated peripheral non-small-cell lung cancer lesion that is no more than 3 cm in size is covered when both of the following criteria is met:

- Surgical resection 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 is covered when all of the following criteria is met:

- In order to preserve lung function when surgical resection or radiation treatment is likely to substantially worsen pulmonary status; OR when the individual 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,
- No more than 3 tumors per lung should be ablated; and,
- Tumors should be amenable to complete ablation; and,
- Twelve months should elapse before a repeat ablation is considered.

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

- In individuals 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

Medicare Advantage Plans and Commercial Products:

Prior authorization is recommended and obtained via the online tool for participating providers. See the Related Policies section.

POLICY STATEMENT

Radiofrequency ablation of tumors is covered for individuals who meet the medical criteria listed above; all other indications outside the liver, including, but not limited to tumors of the breast, head and neck, thyroid, pancreas, adrenal gland, ovary and pelvic/abdominal metastases of unspecified origin are considered not covered for Medicare Advantage Plans and not medically necessary for Commercial Products as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE

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

BACKGROUND

RFA is being evaluated to treat various tumors, including inoperable tumors, or to treat individuals ineligible for surgery due to age, presence of co-morbidities, 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 individuals 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 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).

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 individuals 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 individuals 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 metalwork). Other possible risks include avascular necrosis of the femoral 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, and individuals 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.

For individuals who have painful osteoid osteomas who receive RFA, the evidence includes numerous observational studies and systematic reviews 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 individuals. Most individuals (89% to 96%) remained pain-free when assessed during longer-term follow-up. Another systematic review reported similar success rates noting an average 8.3% failure rate among individuals receiving computed tomography-guided RFA. 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 an improvement in the net health outcome.

Palliation for Bone Metastases

After lung and liver, bone is the third most common metastatic site and is relatively frequent among individuals 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 individuals, 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.

For individuals who have painful osteolytic bone metastases who have failed or are poor candidates for standard treatments who receive RFA, the evidence includes a prospective cohort study and case series. Relevant outcomes are symptoms, change in disease status, quality of life (QOL), medication use, and treatment-related morbidity. A prospective cohort study and case series have shown clinically significant pain relief (defined as a decrease of 2 units from baseline on the Brief Pain Inventory scale) or reduction in opioid use following treatment of painful osteolytic metastases. A multicenter, prospective study reported significant reductions in pain through the 6-month follow-up period, with 59% of individuals achieving immediate improvement in pain within 3 days of RFA. The population is comprised of individuals 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 an improvement in the net health outcome.

Primary Pulmonary Tumors

Surgery is the current treatment of choice in individuals with stage 1 primary non-small-cell lung cancer (NSCLC; stage 1 includes 1a: T1N0M0 and 1b: T2N0M0). Approximately 20% of individuals 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%. Large differences in survival outcome are observed after surgery in stage 1 disease individuals, 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%.

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

Stereotactic body radiotherapy (SBRT) 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 3-year local control rates of stage 1 NSCLC with SBRT have ranged from 80% to 95%. SBRT has been investigated in individuals unfit to undergo surgery, with survival rates similar to surgical outcomes. RFA also is being investigated in individuals with small primary lung cancers or lung metastases who are deemed medically inoperable. The purpose of RFA in individuals who have inoperable primary pulmonary tumors or nonpulmonary tumors metastatic to the lung is to provide a treatment option that is an alternative to or an improvement on existing therapies.

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 individuals 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% to27%. In general, the evidence suggests that RFA results in adequate survival and tumor control in individuals who are not surgical candidates, with low morbidity rates. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Breast Tumors
The treatment of small breast cancers 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 individual'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 individuals with tumors near the skin or chest wall.

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 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
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.

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. Systematic reviews have demonstrated that RFA results in a significant reduction in thyroid nodule size with a 2020 review showing that these changes remain durable through at least 36 months and a 2024 review indicating durability up to 5 years. Complication rates are generally low, but include voice changes. The data are limited by significant heterogeneity in meta-analyses, a lack of generalizability to populations outside Republic of Korea and Italy, and a lack of comparators more relevant to practice in the United States. Further studies comparing RFA to percutaneous ethanol injection (PEI) or surgery would be more informative in determining the potential utility of RFA in individuals with symptomatic or large benign thyroid tumors as these are the recommended treatment options per the American Thyroid Association. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Head and Neck Cancer
In individuals 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.

For individuals who have miscellaneous tumors (eg, 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 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.

CODING

Medicare Advantage Plans and Commercial Products
The following codes are considered medically necessary when the criteria above has been met:

20982 Ablation therapy for reduction or eradication of 1 or more bone tumors (eg, metastasis) including adjacent soft tissue when involved by tumor extension, percutaneous, including imaging guidance when performed; radiofrequency

32998 Ablation therapy for reduction or eradication of 1 or more pulmonary tumor(s) including pleura or chest wall when involved by tumor extension, percutaneous, including imaging guidance when performed, unilateral; radiofrequency

The following codes are considered not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

60660 Ablation of 1 or more thyroid nodule(s), one lobe or the isthmus, percutaneous, including imaging guidance, radiofrequency (New Code Effective 1/1/2025)

60661 Ablation of 1 or more thyroid nodule(s), additional lobe, percutaneous, including imaging guidance, radiofrequency (list separately in addition to code for primary procedure) (New Code Effective 1/1/2025)

There are no specific CPT codes for indications including, but not limited to tumors of the breast, head and neck, pancreas, adrenal gland, ovary and pelvic/abdominal metastases of unspecified origin therefore the appropriate unlisted CPT code should be used.

RELATED POLICIES

Preauthorization via Web-Based Tool for Procedures

PUBLISHED

Provider Update, January/November 2024
Provider Update, January 2023
Provider Update, December 2021
Provider Update, January 2021
Provider Update, December 2019

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