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Subject: Radiofrequency Ablation of Solid Tumors Other Than Liver Tumors

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DESCRIPTION:

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 through the electrodes. The local 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 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.

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.

Ablation systems are approved by the Food and Drug Administration (FDA) under the 510(k) process as a Class II electrosurgical cutting and coagulation device and accessories (e.g., Valleylab Cool-tip™ RF Ablation System, 2006). The Valleylab Cool-tip RF System (generator and accessories) is intended for the use in percutaneous, laparoscopic, intraoperative coagulation and ablation of tissue, such as partial or complete ablation of non-resectable liver lesions and osteoid osteoma tumors within bone.

Summary and Analysis of Evidence: There is published medical evidence in the peer-reviewed literature regarding the safety and efficacy of radiofrequency ablation for (bone metastases, osteoid osteomas, renal cell carcinoma, non-small cell lung cancer, non-pulmonary tumor).

The efficacy and complications of CT-guided radiofrequency ablation (RFA) of spinal osteoid osteoma (OO) was evaluated. Between 2002 and 2012, a total of 61 patients (46 male and 15 female, mean age

26.4 ± 12.7 years) were subjected to RFA for spinal OO. The diagnosis of OO was made after a period of pain and symptoms of 20.6 ± 14.4 months. RFA was performed under conscious sedation and local analgesia. Clinical symptoms were evaluated at 3, 6, and 12 months, and at the end of the time of the present investigation. Mean follow-up was 41.5 ± 7.1 months. The primary efficacy of RFA, complete regression of symptoms, was obtained in 57 out of 61 patients (93.4%). Four out of 61 (6.5%) patients showed a relapse of OO (after 3 months); 2 out of 4 were subjected to a second RFA, the remaining ones were subjected to surgery. There was one complication (case of lower limb paresthesia for 30 days after the ablation) and one possible complication (a disc herniation). The authors concluded that CT-guided RFA is an excellent treatment for spinal OO. Our data suggest that this procedure should be considered for the first stage of therapy for this disease (Albisinni et al 2017).

In a single-center retrospective study, Lassalle et al (2017) assessed the long-term outcome of computed tomography-guided radiofrequency ablation (CT-guided RFA) in patients with suspected osteoid osteoma (OO). Patients with clinical suspicion and imaging diagnosis of osteoid osteoma were treated by CT-guided RFA using the same device with either a 7- or 10-mm active tip electrode. Specific precautions were applied in case of articular or spinal OO. Patients were contacted by phone to evaluate the long-term outcome in terms of pain, ability to perform daily activities (including sports), and long-term complications. Success was defined as the absence of residual pain and ability to perform daily activities normally. From 2008 to 2015, 126 patients were treated by CT-guided RFA for OO in our institution. Mean patient age was 26.1 years (SD = 11, range 1-53); mean delay to diagnosis was 16.9 months (SD = 15.2, range 1-120). Among patients who answered the follow-up call (n = 88), the overall success rate was 94.3%: 79/88 (89.8%) had primary success of the procedure, and 4/88 (4.5%) had a secondary success (repeat-RFA after pain recurrence). Mean follow-up time was 34.6 months (SD = 24.7, range 3-90). Few complications occurred: two mild reversible peripheral nerve injuries, one brachial plexus neuropathy, one broken electrode tip fragment, and one muscular hematoma. The authors concluded that Osteoid osteoma can be effectively and safely treated by CT-guided RFA using the presented ablation protocol. Beneficial effects of the treatment persist at long-term follow-up.

To retrospectively evaluate the technical success, mid-term and long-term efficacy and safety of radiofrequency and microwave ablation in patients with small renal tumors. Over the course of 10 years, 91 ablation procedures in 64 patients for 68 tumors, of size 12-60 mm, were performed using only conscious sedation. These ablations were done under the guidance of computed tomography. We treated 41 males and 23 females with solitary kidney tumors (14 cases) and tumors in non-surgical candidates (54 cases). In 50 (73.5%) tumors single treatment was successful; in 13 (19.1%) cases a second procedure was used successfully, and in the 5 largest tumors (sizes 45-60 mm, 7.4%) a third treatment was necessary. Within the follow-up 10 (15.6%) patients died, but none due to metastatic renal cell carcinoma. Only 1 serious complication was observed - retroperitoneal and psoatic hematoma. Early recurrence occurred in 18 (26.5%) tumors. Late recurrence was detected in 5 (7.4%) cases. In all cases complete local control of the renal tumors was reached. The authors concluded that Percutaneous ablation is a very effective treatment for patients with small renal tumors of the T1a group with a minimal complication rate (Dvorak et al 2017).

Iannuccilli et al (2016) defined effectiveness and safety of CT-guided radiofrequency ablation (RFA) of renal tumours and prognostic indicators for treatment success. Patients with a single treatment of a solitary, biopsy-proven renal tumour with intent to cure over a 14-year period were included (n = 203). Probability of residual disease over time, complication rates and all-cause mortality were assessed in

relation to multiple variables. Mean tumour size was 2.5 cm (range 1.0-6.0). Mean follow-up was 34.1 months (range 1-131). There was an increase in likelihood of residual disease for tumours ≥ 3.5 cm ($P < 0.05$), clear cell subtype of renal cell carcinoma ($P \leq 0.005$) and maximum treatment temperature $\leq 70^\circ\text{C}$ ($P < 0.05$). There was a decrease in likelihood of residual disease for exophytic tumours ($P = 0.01$) and no difference based on age, gender, tumour location or type of radio frequency (RF) electrode used. Major complications occurred in 3.9 %. Median post-treatment survival was 7 years for patients with tumours < 4 cm, and 5-year overall survival was 80 %. Probability of minor complication increased with tumour size ($P = 0.03$), as did all-cause mortality ($P = 0.005$). The authors concluded that CT-guided RFA is safe and effective for early-stage renal cancer, particularly for exophytic tumours measuring < 3.5 cm. Overall 5-year survival with tumours < 4 cm is comparable to partial nephrectomy.

Akhan et al (2016) evaluated the survival benefit achieved with radiofrequency (RF) ablation of primary and metastatic lung tumors and determine significant prognostic factors for recurrence-free survival. Forty-nine patients with lung cancer (10 primary and 39 metastatic) underwent computed tomography-guided percutaneous RF ablation between June 2005 and October 2013. A total of 112 tumors (101 metastatic and 11 primary non-small cell lung cancer) were treated with RF ablation. Tumor diameter ranged from 0.6 to 4 cm (median 1.5 cm). Effectiveness of treatment, complications, and survival were analyzed. Primary success rate was 79.5% and local tumor progression occurred in 23 tumors. Among tumors showing progression, 10 were re-treated with RF ablation and secondary success rate was 87.5%. One-, two-, and three-year overall survival rates of 10 patients with primary lung cancer were 100%, 86%, and 43%, respectively. One-, two-, three-, four-, and five-year overall survival rates for 39 patients with metastatic lung tumors were 90%, 73%, 59%, 55%, and 38%, respectively. One-, two-, three-, and four-year overall survival rates for 16 patients with colorectal pulmonary metastases were 94%, 80%, 68%, and 23%, respectively. Complications occurred in 30 sessions (24.6%). Pneumothorax occurred in 19 sessions with seven requiring image-guided percutaneous chest tube drainage. Tumor status (solitary or multiple) and presence of extrapulmonary metastasis at initial RF ablation were significant prognostic factors in terms of recurrence-free survival. The authors concluded that RF ablation is a safe and effective treatment with a survival benefit for selected patients with primary and secondary lung tumors.

In a prospective multicenter study, Dupuy et al (2015) evaluated the 2-year overall survival rate, adverse event rate, local control rate, and impact on pulmonary function tests for medically inoperable patients with stage IA non-small cell lung cancer (NSCLC) undergoing computed tomography (CT)-guided radiofrequency ablation (RFA). Fifty-four patients (25 men and 29 women) with a median age of 76 years (range, 60-89 years) were enrolled from 16 US centers; 51 patients were eligible for evaluation (they had biopsy-proven stage IA NSCLC and were deemed medically inoperable by a board-certified thoracic surgeon). Pulmonary function tests were performed within the 60 days before RFA and 3 and 24 months after RFA. Adverse events were recorded and categorized. Patients were followed with CT and fludeoxyglucose positron emission tomography. Local control rate and recurrence patterns were analyzed. The overall survival rate was 86.3% at 1 year and 69.8% at 2 years. The local tumor recurrence-free rate was 68.9% at 1 year and 59.8% at 2 years and was worse for tumors > 2 cm. In the 19 patients with local recurrence, 11 were re-treated with RFA, 9 underwent radiation, and 3 underwent chemotherapy. There were 21 grade 3 adverse events, 2 grade 4 adverse events, and 1 grade 5 adverse event in 12 patients within the first 90 days after RFA. None of the grade 4 or 5 adverse events were attributable to RFA. There was no significant change in the forced expiratory volume in the first second

of expiration or the diffusing capacity of lung for carbon monoxide after RFA. A tumor size less than 2.0 cm and a performance status of 0 or 1 were associated with statistically significant improved survival of 83% and 78%, respectively, at 2 years. The authors concluded that RFA is a single, minimally invasive procedure that is well tolerated in medically inoperable patients, does not adversely affect pulmonary function tests, and provides a 2-year overall survival rate that is comparable to the rate reported after stereotactic body radiotherapy in similar patients.

POSITION STATEMENT:

Note: For radiofrequency ablation of liver tumors, refer to [Radiofrequency Ablation of Liver Tumors, 02-40000-23](#).

Radiofrequency ablation (RFA) **meets the definition of medical necessity** for the following indications:

- Palliative treatment of pain in members with osteolytic bone metastases who have failed or are poor candidates for standard treatment such as radiation or opioids, **OR**
- Osteoid osteomas that cannot be managed with medical treatment (e.g., nonsteroidal anti-inflammatory drugs (NSAIDs), surgical excision); **OR**
- Localized renal cell carcinoma that is no more than 4cm in size when either of the following criteria is met:
 - In order to preserve kidney function in members with significantly impaired renal function (i.e., the member has 1 kidney or renal insufficiency defined by a glomerular filtration rate of less than 60 mL/min/m²); **AND**
 - When the standard surgical approach (i.e., resection of renal tissue) is likely to substantially worsen existing kidney function; **OR**
 - The member is not considered a surgical candidate.
- An isolated peripheral non-small cell lung cancer lesion that is no more than 3 cm in size 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 that are no more than 3 cm in size when **ALL** of the following criteria are met:
 - RFA is being performed in order to preserve lung function when surgical resection or radiation treatment is likely to substantially worsen pulmonary status **OR** the member 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**
 - There are no more than 3 tumors per lung being ablated; **AND**
 - The tumors are amenable to complete ablation; **AND**

- If repeat ablation is planned, twelve months should have elapsed before a repeat ablation is considered.

Radiofrequency ablation (RFA) for all other indications, including but not limited to the following is considered **experimental or investigational**, the evidence is insufficient to determine the effects of RFA on health outcomes:

- Initial treatment of painful bony metastases;
- Breast cancer;
- Breast fibroadenomas;
- Lung cancer not meeting the criteria above;
- Prostate cancer;
- Osteoid osteomas that can be managed with medical treatment (e.g., nonsteroidal anti-inflammatory drugs (NSAIDs), surgical excision);
- Renal cell carcinoma not meeting the criteria above; **AND**
- All other tumors outside the liver including, but not limited to, the following:
 - Breast tumors
 - Head and neck
 - Adrenal gland
 - Ovary
 - Pelvic/abdominal metastases of unspecified origin
 - Thyroid.

BILLING/CODING INFORMATION:

CPT Coding:

20982	Ablation therapy for reduction or eradication of 1 or more bone tumors (e.g., 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
50542	Laparoscopy, surgical; ablation of renal mass lesion(s)
50592	Ablation, one or more renal tumor(s), percutaneous, unilateral, radiofrequency

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

LOINC Codes:

The following information may be required documentation to support medical necessity: Physician history and physical, initial assessment, procedure note, visit note.

Documentation Table	LOINC Codes	LOINC Time Frame Modifier Code	LOINC Time Frame Modifier Codes Narrative
Physician history and physical	28626-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Physician Initial Assessment	18736-9	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Physician procedure note	11505-5	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Attending physician visit note	18733-6	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.

REIMBURSEMENT INFORMATION:

Refer to section entitled [POSITION STATEMENT](#).

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline reviewed date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at [Coverage Protocol Exemption Request](#).

DEFINITIONS:

Ablation: removal of a body part or destruction of its function.

Osteoid osteomas: benign tumors of the bone typically seen in children and young adults. They cause inflammation, local effects on normal tissue from tumor expansion, and secondary effects and complications (e.g., scoliosis, osteoarthritis).

Radiofrequency ablation (RFA): uses high-energy radio waves for treatment. A thin, needle-like probe temporarily placed into the tumor releases these radio waves. Placement of the probe is accurately guided by ultrasound or CT scans. The probe releases high frequency alternating current that creates frictional heating and destroys the cancer cells.

Unresectable: a property of a tumor where it is unable to be removed surgically.

RELATED GUIDELINES:

[Radiofrequency Ablation of Liver Tumors, 02-40000-23](#)

OTHER:

None applicable.

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 10/24/24.

GUIDELINE UPDATE INFORMATION:

03/15/04	New Medical Coverage Guideline.
03/15/05	Scheduled review with revisions consisting of adding coverage criteria regarding palliation of osteolytic bone lesions and osteomas.
01/01/06	Annual HCPCS coding update (added 50592).
03/15/06	Scheduled review; no change in coverage statement.
01/01/07	Annual HCPCS coding update (added 32998).
04/15/07	Scheduled review; added inoperable renal masses as a covered indication; added CPT code 50542.
05/15/07	Reformatted guideline.
04/15/08	Scheduled review; no change in position statement; references updated.
04/15/09	Scheduled review; description section revised; no change in position statement; references updated.
01/01/10	Annual HCPCS coding update: simple revision of descriptor for code 32998.
05/15/11	Scheduled review; position statement unchanged; references updated; formatting changes.
09/15/11	Revision; formatting changes.
11/15/12	Annual review; position statement and references updated; formatting changes.
11/15/13	Annual review; position statement updated to include reference to thyroid tumors; Program Exceptions section updated; references updated; other formatting changes.
11/15/14	Annual review; position statement unchanged; references updated.
01/01/15	Annual coding update: revised 20982.
11/15/17	Review; updated description and references. Reformatted position statements. Added position statement and criteria for localized renal cell carcinoma. Revised experimental/investigational position statement (added prostate cancer).
01/01/18	Annual HCPCS code update. Revised 32998 code descriptor.
10/15/19	Review; no change in position statement. Deleted code 76940. Updated references.
11/15/21	Review; no change in position statement. Updated references.
08/21/23	Update to Program Exceptions section.
11/15/23	Review; no change in position statement. Updated references.
11/15/24	Review; no change in position statement. Updated references.