MEDICAL POLICY

Medical Policy Title	**Thermal Ablation for Solid Tumor Treatment**
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Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Radiofrequency Tumor Ablation

A. Radiofrequency ablation (RFA) is considered a **medically appropriate** treatment option for **hepatocellular carcinoma** for **EITHER** of the following conditions:

1. Individual is not a surgical candidate (e.g., location of lesion[s], existence of comorbid conditions) and Milan criteria is met (e.g., a single tumor of less than or equal to 5 cm or up to three [3] lesions no greater than 3 cm in diameter);
2. As a bridge to transplant when the individual meets liver transplant criteria and is awaiting liver transplantation.

B. RFA is considered a **medically appropriate** treatment option for the **primary treatment of hepatic metastases** for **ALL** of the following conditions:

1. Individual is not a surgical candidate (e.g., location of lesions, existence of comorbid conditions);
2. Metastases meet the Milan criteria (e.g., a single tumor of less than or equal to 5 cm or up to three [3] lesions no greater than 3 cm in diameter);
3. The patient has no evidence of uncontrolled extrahepatic systemic metastatic disease.

C. Percutaneous RFA of an **osteoid osteoma** is considered a **medically appropriate** alternative to surgical excision when the individual cannot be managed successfully with medical management.

D. RFA is considered **medically appropriate** when utilized for palliation of pain in individuals with **osteolytic bone metastases** who have failed or are poor candidates for standard treatments such as opioids or radiation.

E. RFA of **localized renal cell carcinoma** is considered **medically appropriate** when the following criteria are met:

1. Lesion size is 4 cm or less in diameter; and **EITHER**
   a. The individual is not a surgical candidate (e.g., location of lesion[s], existence of comorbid conditions); **or**

b. Treatment is necessary to preserve kidney function in individuals with significantly impaired renal status (i.e., the individual has one (1) kidney or renal insufficiency as defined by a glomerular filtration rate of <60mL/min/m2); and standard treatment is likely to substantially worsen kidney function.

F. RFA is considered **medically appropriate** to treat **non-small cell lung cancer (NSCLC**) when **BOTH** of the following conditions are met:

1. Isolated and peripheral lesion is 3 cm or less in size;
2. Individual is not a surgical candidate. 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.

G. RFA is considered **medically appropriate** to treat **non-pulmonary tumor(s) metastatic to the lung** for the following conditions:

1. Surgical resection or radiotherapy is likely to worsen pulmonary status substantially and ablation would be necessary to preserve lung function;
2. The individual is not a surgical candidate (e.g., location of lesion[s], existence of comorbid conditions), and **ALL** of the following criteria are met:
   a. Tumor size is 3 cm or less;
   b. There is no evidence of extrapulmonary metastases;
   c. There are no more than three (3) tumors per lung to be ablated;
   d. Tumors are amenable to complete ablation; **and**
   e. Twelve months have elapsed since the last ablation.

H. Laparoscopic, transcervical ultrasound-guided RFA (e.g., the Acessa System, Sonata Device) is considered **medically appropriate** as an alternative to hysterectomy or myomectomy for the treatment of **uterine fibroid tumors**, when **ALL** the following criteria are met:

1. Individual is aged 18 years or older;
2. Individual is premenopausal;
3. Evidence from ultrasound demonstrates that fibroids are less than 10 cm in diameter for laparoscopic RFA with Acessa or 7 cm for transcervical RFA with Sonata;
4. Symptoms are persistent, directly attributed to the uterine fibroid(s), and include **ANY** of the following:
   a. Excessive menstrual bleeding (menorrhagia);
   b. Pelvic pain or pressure;
   c. Gastrointestinal symptoms related to compression of the bowel (e.g., constipation, bloating);

d. Urinary symptoms related to compression of the ureter or bladder (e.g., urinary frequency, urgency); **or**

e. Dyspareunia (pain during sexual relations).

I. RFA is considered **investigational** as a treatment method for any other solid tumors, including, but not limited to pancreatic, thyroid, and breast tumors.

II. Cryosurgical Ablation

A. Cryosurgical ablation (CA) of **localized renal cell carcinoma** is considered a **medically appropriate** for the following conditions:

1. Lesion size is 4 cm or less in diameter; and **EITHER**

a. The individual is not a surgical candidate (e.g., location of lesion[s], existence of comorbid conditions); **or**

b. Treatment is necessary to preserve kidney function in individuals with significantly impaired renal status (i.e., the individual has one (1) kidney or renal insufficiency as defined by a glomerular filtration rate of <60mL/min/m2); and standard treatment is likely to substantially worsen kidney function.

B. CA may be considered a **medically appropriate** treatment option for individuals with **lung cancer** for the following conditions:

1. Individual requires palliation for a central airway obstructing lesion;

2. Diagnosis is early-stage non-small cell lung cancer and **BOTH** of the following are met:

a. Individual is not receiving stereotactic radiotherapy or definitive radiation therapy; **and**

b. Individual is considered “high risk” as a poor surgical candidate (see Professional Guidelines section; NCCN Guidelines for NSCLC, for guidance on what is considered “high risk”).

C. CA is considered **medically appropriate** when utilized for palliation of pain in individuals with osteolytic bone metastases who have failed or are poor candidates for standard treatments such as opioids or radiation.

D. CA is considered **investigational** as a treatment method for any other tumor, including but not limited to, primary/metastatic liver malignancies, breast tumors (benign and malignant), and pancreatic cancer.

III. Microwave Ablation

A. Microwave ablation (MWA) is considered **medically appropriate for primary or metastatic hepatic tumors** when **BOTH** of the following conditions are met:

1. Individual is not a surgical candidate (e.g. location of lesion[s], existence of comorbid conditions);

2. Milan criteria is met (e.g., a single tumor of less than or equal to 5 cm or up to three [3] nodules no greater than 3 cm in diameter).

B. MWA is considered **medically appropriate** for **primary or metastatic lung tumors** when **ALL** the following conditions are met:

1. Individual is not a surgical candidate (e.g. location of lesion[s], existence of comorbid conditions);
2. Individual will not be receiving stereotactic radiotherapy or definitive radiation therapy;
3. Treatment is for a tumor that is 3 cm or less in size.

C. MWA is considered **medically appropriate** for renal cell carcinoma when **ALL** the following conditions are met:

1. Individual is not a surgical candidate (e.g. location of lesion[s], existence of comorbid conditions);
2. Biopsy of lesions is recommended to be done prior to or at time of ablation;
3. Treatment is for a tumor that is 3 cm or less in size.

D. MWA is considered **medically appropriate** when utilized for palliation of pain in individuals with osteolytic bone metastases who have failed or are poor candidates for standard treatments such as opioids or radiation.

E. MWA for the treatment of primary or metastatic tumors other than liver, lung, kidney or bone is considered **investigational**.

RELATED POLICIES

Corporate Medical Policy

7.01.01 Focal Therapies for Prostate Cancer Treatment

7.02.07 Liver Transplantation

6.01.12 Stereotactic Radiosurgery and Stereotactic Body Radiation Therapy

7.01.69 Transarterial Radioembolization (TARE) for Hepatic Tumors

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

Documentation should include the relevant history and physical demonstrating the tumor type, the rationale of why the tumor is unresectable (if applicable), size of tumor(s) to be treated, and ablation modality to be utilized.

DESCRIPTION

Surgical resection is the standard treatment for many solid tumor types, and despite advances in surgical techniques, many patients are either considered inoperable for surgery or prefer a nonsurgical minimally invasive local treatment. For individuals who meet specific criteria given the location, tumor size and type, thermal ablation can be offered as an alternative. The most common ablative modalities are radiofrequency ablation (RFA), microwave ablation (MWA) and Cryoablation (CA). RF and MWA utilize thermal/heat-based techniques and CA uses thermal/cold-based techniques (i.e., freezing) to destroy tissues. Per the National Comprehensive Cancer Network (NCCN), each ablation energy modality has advantages and disadvantages, therefore, determination of the modality utilized should take into consideration the size and location of the target tumor, risk of complication, as well as local expertise and/or operator familiarity.

Radiofrequency Ablation

RFA is the oldest and most frequently utilized thermal ablative technique and can be administered percutaneously, by open or laparoscopic surgery. This modality relies on heat to destroy tumors by thermal coagulation and protein denaturation. High frequency alternating current flows from un-insulated electrode tips into surrounding tissue. As the tissue ions attempt to follow the change in direction of the alternating current, ionic agitation results in frictional heating. The tissue surrounding the electrode, rather than the electrode itself, is the primary source of heat. It is presumed that tissue heating drives extracellular and intracellular water out of the tissue, resulting in coagulative necrosis.

RFA is typically used to treat inoperable tumors or to treat patients who are ineligible for surgery due to advanced age or co-morbidities. RFA was developed initially to treat inoperable tumors of the liver and is now utilized as a minimally invasive treatment alternative for other solid tumors, such as lung, renal, bone, and uterine fibroids.

Cryosurgical Ablation

Cryosurgical ablation (CA) is a method of thermal tumor ablation in which subfreezing temperatures are delivered through penetrating or surface cryoprobes in which a cryogen is circulated. Cell death is caused by direct freezing, denaturation of cellular proteins, cell membrane rupture, cell dehydration and ischemic hypoxia. Cryosurgical ablation may be used for the destruction of metastatic tumors in situ or for the destruction of microscopic residual carcinoma in the case of close surgical margins. It may be performed as an open surgical technique or as a closed procedure.

Several CA devices have been cleared for marketing by the FDA through the 510(k) process for use in open, minimally invasive, or endoscopic surgical procedures in the areas of general surgery, urology, gynecology, oncology, neurology, dermatology, proctology, thoracic surgery, and surgeries of the ear, nose, and throat. Examples include: Cryocare Surgical System (Endocare); CryoGen Cryosurgical System (Cryosurgical); CryoHit (Galil Medical) for the treatment of breast fibroadenoma; IceSense3, ProSense, MultiSense Systems (IceCure Medical); SeedNet System (Galil Medical); and Visica System (Sanarus Medical). FDA product code: GEH.

CA has been investigated for its efficacy in the treatment of liver, lung, kidney, bone, breast, cervical cancer, neuroendocrine tumors and prostate cancer. CA for the treatment of prostate cancer is not addressed in this policy.

Microwave Ablation

Microwave ablation (MWA) is similar to RFA and CA as a form of thermal ablation. However, MWA has potential advantages over both. MWA uses microwave energy to heat and coagulate the tissue adjacent to the probe, resulting in a small, 2 cm to 3 cm elliptical area of tissue ablation. In tumors greater than 2 cm in diameter, 2 to 3 antennas may be used simultaneously to increase the targeted area and shorten the operative time. The use of multiple antennas can reduce the operative time by 20%-30%. The higher temperatures reached with MWA (>100°C) can overcome the "heat sink" effect occurring in RFA, in which tissue cooling occurs from nearby blood flow in large vessels, potentially resulting in incomplete tumor ablation. Microwave ablation does not rely on the conduction of electricity for heating and, therefore, does not flow electrical current through patients. Grounding pads are not required because there is no risk of skin burns. Additionally, MWA does not produce electric noise, which allows ultrasound guidance during the procedure without interference, unlike RFA.

Multiple MWA devices have been cleared for marketing by the FDA through the 510(k) process. These devices are indicated for soft tissue ablation, including partial or complete ablation of nonresectable liver tumors. Some devices are specifically cleared for use in open surgical ablation, percutaneous ablation, or laparoscopic procedures. The FDA used determinations of substantial equivalence to existing radiofrequency and MWA devices to clear these devices. Examples include: MedWaves Microwave Coagulation/Ablation System (MedWaves Inc.), MicroThermX Microwave Ablation System (BSD Medical Corporation), Emprint Ablation System (Medtronic), Cetus (Johnson & Johnson), and NEUWAVE Flex Microwave Ablation System (Johnson and Johnson), FDA product code: NEY.

MWA was first used percutaneously as an adjunct to liver biopsy. It has since been investigated for its efficacy in the treatment of hepatocellular carcinoma, breast cancer, colorectal cancer metastatic to the liver, renal cell carcinoma, renal hamartoma, adrenal malignant carcinoma, non-small cell lung cancer, intrahepatic primary cholangiocarcinoma, secondary splenomegaly and hypersplenism, abdominal tumors and other tumors not amenable to resection. It is also being assessed to determine whether it can reduce the incidence of tumor progression while awaiting transplantation to maintain an individual's ability to meet transplant criteria.

SUPPORTIVE LITERATURE

Uterine Fibroids

RFA was FDA approved as a treatment for symptomatic myomas in 2012 and has been shown to reduce heavy menstrual bleeding, pelvic pain, and other associated symptoms. The RFA system Acessa for uterine fibroids, received FDA clearance for marketing in 2012 (K121858). The device is indicated for use in percutaneous, laparoscopic coagulation and ablation of soft tissue, including

treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance. The next generation of the Acessa System, The Acessa ProVu System, received FDA clearance in 2018. It is indicated for use in percutaneous, laparoscopic coagulation and ablation of soft tissue, including treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance. In the Acessa procedure, a controlled volume of heat is applied directly to the fibroid, killing the tissue of the fibroid while leaving healthy surrounding tissue unharmed. The dead tissue is reabsorbed by the body.

Rattray et al (2018) published the results of the TRUST Canada study, reporting on the clinical outcomes of pre-and post-laparoscopic RFA for 45 individuals who were greater than 18 years of age, premenopausal, with symptomatic uterine fibroids less than 10 cm in size, a uterine size less than or equal to 16 gestational weeks, a desire for uterine conservation, and were not pregnant or lactating. RFA was compared to individuals receiving a myomectomy. The primary endpoint of hospitalization time was 6.7±3.0 hours for the RFA group and 9.9±10.7 hours for the myomectomy group. Intraoperative blood loss was lesser for RFA subjects at 25.2±21.6 versus 82.4±62.5 mL (p=0.0002) for the myomectomy group. RFA procedures took lesser time (70.0 versus 86.5 minutes for myomectomy procedures). At 3 months, both cohorts reported the same significant symptom severity reduction (-44.8%; P<0.0001). RFA subjects took lesser time from work: 11.1±7.6 versus 18.5±10.6 days (P=0.0193). One myomectomy subject was hospitalized overnight after experiencing a 20-second asystole during the procedure. One RFA subject underwent a reintervention. The combined per patient direct and indirect costs of the two procedures were comparable.

The TRUST United States trial had a preliminary analysis with a planned follow-up of 5 years conducted by Yu and associates (2022). The RCT will compare laparoscopic RFA or myomectomy in patients with uterine myoma. Inclusion criteria were the same as the TRUST Canada trial. The study is evaluating 29 patients who underwent laparoscopic RFA and 27 patients who underwent myomectomy. Primary outcome was again hospital stay, which was significantly shorter in the laparoscopic RFA group (8.01±5.7 hours) than the myomectomy group (18.8 ±14.6 hours; P<.05). Outcomes of interest for the primary analysis were symptoms and patient reported quality of life at 12 months. Symptoms improved in both groups at both 3 and 12 months with no statistical difference between the two. Symptom severity and health-related quality of life were significantly better in the myomectomy group at 12 months. Major complications occurred in 2 patients in the myomectomy group and 1 patient who had RFA. The study was limited by its lack of blinding, to both the treatment and treating physician.

Miller and colleagues (2019) investigated the Sonata device for the treatment of symptomatic uterine fibroids with 2-year outcomes. This prospective multicenter single-arm interventional trial included premenopausal women with up to 10 clinically relevant uterine fibroids ranging from 1 to 5 cm in diameter. The individuals were treated with sonography-guided transcervical fibroid ablation (TFA) and were assessed for symptom severity, health related quality of life, general health status, work and activity limitations, treatment satisfaction, adverse events, surgical reintervention, and occurrence of pregnancy and associated outcomes. Of the 147 women who were enrolled, 85% (125/147) returned for 2-year follow up. Symptom severity decreased from 55 ± 19 to 24 ± 18 (P < 0.001), health-related quality of life increased from 40 ± 21 to 83 ± 19 (P < 0.001). Overall treatment satisfaction at 2 years was 94%. The mean percentage of missed work time, overall work

impairment, and activity impairment significantly decreased at follow-up. Through 2 years, surgical reintervention for heavy menstrual bleeding was performed in 5.5% of patients. One singleton pregnancy occurred with a normal peripartum outcome. The authors concluded that treatment with the Sonata system provides a significant clinical improvement through 2 years post-ablation.

Renal Tumors

Renal ablation traditionally has been reserved for patients who are poor candidates for surgery or in whom renal preservation is of utmost priority. However, with some reports on oncologic efficacy approaching that of partial nephrectomy (PN), renal ablation can be considered as a first-line treatment option for patients who meet specific criteria.

Yanagisawa et al (2022) published a systematic review and meta-analysis comparing ablative therapies (cryoablation, radiofrequency ablation, and microwave ablation) to partial nephrectomy. Twenty-seven trials (N=13,996) were included; 12 of those studies directly compared cryoablation with partial nephrectomy, however, the results were not stratified by modality. No significant differences in cancer-specific mortality for cT1a tumors (p=.50) and cT1b tumors (p=.63) were found when comparing partial nephrectomy and ablation therapies. Local recurrence was higher for ablative therapies compared with partial nephrectomy in both cT1a tumors (risk ratio, 0.43; 95% confidence interval [CI], 0.28 to 03.66; p=.0001) and cT1b tumors (risk ratio, 0.41; 95% CI, 0.23 to 0.75; p=.004). There were no significant differences between partial nephrectomy and ablation therapy in terms of rate of metastases, overall complications, and decline in renal function.

Lim et al (2020) completed a study to evaluate the immediate and 3- and 5-year outcomes of patients with clinical stage T1 (cT1) biopsy-proven RCC who were treated by percutaneous cryoablation. A total of 180 patients with 185 separate cT1 RCC lesions were identified. Mean patient age was 68.4 years (range, 34.1–88.9 years) and 52 patients (28.9%) were women. There were 168 (90.8%) and 17 (9.2%) cT1a and cT1b lesions, respectively, with a mean lesion size of 28.5 mm (range, 11–58 mm). Technical success was achieved in 98.9% of patients. The major complication rate was 2.2%. Residual unablated tumor on the first follow-up scan was identified in four of 183 tumors (2.2%). Estimated local tumor progression-free survival at 3 and 5 years was 98.3% and 94.9%, respectively. No distant metastases or deaths attributable to RCC occurred. Mean estimated glomerular filtration rate before the procedure was 72.4 ± 18.5 (SD) mL/min/1.73 m2 and this was not statistically significantly different after the procedure (69.7 ± 18.8 mL/min/1.73 m2), at 1 year (70.7 ± 16.4 mL/min/1.73 m2), or at 2 years (69.8 ± 18.9 mL/min/1.73 m2 (p> 0.05). The authors concluded that this data adds to the accumulating evidence that image-guided cryoablation is an efficacious treatment for selected cT1 RCC with a low complication rate and robust 3- and 5-year outcomes.

McClure et al (2023) conducted a systematic review and meta-analysis comparing microwave ablation and cryoablation for renal cell carcinoma. Study arms from RCTs, comparative observational, and single-arm studies were eligible. The outcomes included local tumor recurrence (LTR), overall

survival, disease-free survival, overall/major complications, procedure/ablation time, 1- to 3-month primary technique efficacy, and technical success. Baseline characteristics were similar between groups and mean tumor size for MWA and cryoablation were 2.74 and 2.69 cm. Single-arm meta-analyses were similar for LTR and secondary outcomes between cryoablation and MWA. Ablation time was significantly shorter with MWA than with cryoablation (meta-regression weighted mean difference 24.55 minutes, 95% confidence interval -31.71, -17.38, P < .0001). One-year LTR was significantly lower with MWA than cryoablation (odds ratio 0.33, 95% confidence interval 0.10-0.93, P = .04). There were no significant differences for other outcomes. MWA provides significantly improved 1-year LTR and ablation time compared with cryoablation for patients with RCC. Other outcomes appeared similar or favorable for MWA; however, results were not statistically significant. MWA of primary RCC is as safe and effective as cryoablation, which should be confirmed with future comparative studies.

Liver Tumors

The evidence supporting the use of RFA in the treatment of inoperable hepatic metastases includes an RCT, systematic reviews and meta-analyses, prospective cohort series, and retrospective case series. There are no RCTs comparing RFA with alternative treatments for patients who have unresectable colorectal liver metastases. However, an RCT assessing RFA plus chemotherapy found improved survival at eight (8) years compared with chemotherapy alone. In addition, prospective studies have demonstrated that overall survival following RFA is at least equivalent to and likely better than currently accepted systemic chemotherapy in well-matched patients with unresectable hepatic metastatic colorectal cancer (CRC) who do not have extrahepatic disease. Results from a number of uncontrolled case series also have suggested RFA of hepatic CRC metastases produces long-term survival that is at a minimum equivalent to but likely superior to historical outcomes achieved with systemic chemotherapy. Evidence from a comparative study has indicated RFA has fewer deleterious effects on quality of life than chemotherapy and that RFA patients recover their quality of life significantly faster than chemotherapy recipients. It should be noted that patients treated with RFA in different series might have had better prognoses than those who had chemotherapy, suggesting patient selection bias might at least partially explain the better outcomes observed following RFA. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Mohan et al (2015) published a systematic review of RFA as a treatment for unresectable metastases from neuroendocrine tumors. Seven unique studies (N=301 patients), all retrospective case series from a single institution, were included. The most common tumor type was carcinoid (59%), followed by nonfunctional pancreatic tumors (21%) and functional pancreatic tumors (13%). There were 2 periprocedural deaths (rate, 0.7%), and the overall complication rate was 10%, including hemorrhage, abscess, viscus perforation, bile leak, biliopleural fistula, transient liver insufficiency, pneumothorax, grounding pad burn, urinary retention, pneumonia, and pleural effusion. Improvement in symptoms was reported in 92% (117/127) of symptomatic patients, with a median duration of relief ranging from 14 to 27 months. There was a high degree of variability in the length of follow-up and surveillance, and a wide range of local recurrence rates, from less than 5% to 50%; 5-year survival rates ranged from 57% to 80%.

Fairweather et al (2017) compared the overall survival in patients with neuroendocrine liver metastases (N=649) from a large prospective database. Primary treatment modalities included: systemic therapy (n=316), chemoembolization (n=130), observation (n=117), surgical resection (n=58), and RFA (n=28). The most favorable 10-year overall survival estimates were achieved with surgical resection (70%), followed by RFA (55%), systemic therapy (31%), chemoembolization (28%), and observation (20%).

Most reports of RFA treatment for neuroendocrine liver metastases have assessed small numbers of patients or subsets of patients in reports of multiple ablative methods or small subsets of larger case series of patients with various diagnoses. The available evidence has indicated that durable tumor and symptom control of neuroendocrine liver metastases can be achieved using RFA in individuals whose symptoms are not controlled by systemic therapy or who are ineligible for resection.

For individuals who have hepatic metastases, not of colorectal or neuroendocrine origin who receive RFA, the evidence includes a systematic review, small, nonrandomized comparative studies and small case series. Relevant outcomes are overall-survival, disease-specific survival, symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. For patients who are ineligible for resection, RFA may provide a survival benefit. However, the evidence is limited by study designs with a high-risk of bias and small sample sizes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Glassberg et al (2019) conducted a systematic review and meta-analysis of 16 trials comparing MWA to resection in adults with confirmed HCC or liver cancer. The review included 1 RCT and 15 observational studies (two prospective and 13 retrospective). The studies represented 965 individuals treated with MWA and 755 resections from a period of 15 months to 5 years. Patients who received MWA had a significantly higher risk of local tumor progression compared to those who received resection. At 1-year, overall survival did not differ between MWA and resection but 3- and 5-year overall survival was significantly higher in patients who had received resection. Complications were lower with MWA compared to resection. Additionally, operative time, intraoperative blood loss, and hospital length of stay were significantly lower with MWA. Some studies included patients that were nonresectable in the MWA treatment arm, but due to limited reporting and patient preference affecting which treatment was performed, the reviewers were not able to calculate the number of patients who were nonresectable or to conduct subgroup analyses by resectable versus unresectable tumors. Microwave ablation was typically selected for patients with smaller and/or deeper tumors, more comorbidities, and a preference for a less invasive procedure. The reviewers concluded that MWA can be an effective and safe alternative to hepatic resection in patients or tumors that are not amenable to resection, but more studies are needed to determine the target population that would benefit most from MWA.

Chong and colleagues (2020) conducted an RCT of 93 patients with HCC who had up to three lesions of 5 cm or smaller, Child-Pugh score A or B, the absence of extrahepatic metastases, and absence of radiologic evidence of major vascular or bile duct invasion. The primary outcome of the study was rate of complete ablation at 1 month, which did not differ significantly for MWA. Rates of overall survival up to 5 years and rates of disease-free survival up to 3 years were similar between groups.

Limitations of the study included that sample size calculations were based on complete ablation at one month, so the study may not have been adequately powered to detect differences in the overall survival or disease-free survival.

The body of evidence indicates that MWA is an effective option in patients for whom resection is not an option. Although studies have methodological limitations, they consistently showed that MWA and RFA had similar outcomes with up to 5 years of follow-up in patients with a single tumor ≤ 5cm or up to three nodules ≤ 3 cm each.

Bridge to Liver Transplant

The Milan criteria are used to identify the tumor burden of patients with hepatocellular carcinoma (HCC) as smaller tumors are more likely to allow for a good outcome after liver transplantation. The Milan criteria state that transplantation should be performed in those with a single tumor of 5 cm or less or three (3) tumors that are each 3 cm or less, with no macrovascular invasion, and no metastasis. Patients who do not meet the Milan criteria are not considered eligible candidates for liver transplantation.

The dropout rates of patients with HCC from liver transplant lists have been reported to range from 20-40% due to tumor progression. Recent studies utilizing RFA as a bridge to transplant have increased days on the transplant list considerably and decreased dropout rates to 12-15%.

The evidence related to the use of RFA specifically to downsize/downgrade tumors to meet priority transplant criteria is insufficient at this time due to inconsistent outcomes reported in the literature. Studies regarding tumor recurrence in this patient population which demonstrate a longer-term follow-up are needed.

Bone Tumors

The majority of literature on the use of RFA on patients with bone metastases consists of uncontrolled studies with only a limited number of cases. However, the patient populations enrolled in the studies comprised individuals with limited or no treatment options, for whom short-term pain relief was an appropriate outcome.

Studies investigating the efficacy of RFA for osteoid osteomas provide evidence that RFA achieves outcomes comparable to surgical excision, in terms of tumor destruction and pain relief, and allows for a decrease in hospital stay and quicker postoperative recovery. RFA treatment of osteoid osteoma is not appropriate for large lesions or for those in a location that makes it technically difficult to perform percutaneously.

Jennings et al (2021) reported on a single-arm prospective study of 66 patients with metastatic bone disease who were treated with cryoablation and were not candidates for or had not benefitted from standard therapy. The primary endpoint was the change in pain score from baseline to week 8 and patients were followed for 24 weeks. The mean decrease in pain score from baseline to week 8 was 2.61 points (95% CI, 3.45 to 1.78). Pain scores decreased further after the primary endpoint and reached clinically meaningful levels (more than a 2-point decrease) after week 8. This study had

several limitations, including the lack of a comparator, potential for selection bias, and lack of blinding combined with subjective outcome measures.

Khanmohammadi et al (2023) conducted a systematic review to understand the safety and effects of cryoablation on the pain and quality of life (QoL) of patients with bone metastasis. Inclusion criteria was original studies published until September 8, 2022, studies on patients 18 years and affected by bone metastasis, bone metastasis treated with stand-alone cryoablation, studies reporting patients' pain before and at least one time-point following cryoablation and English language studies. Fifteen studies on 376 patients were included. All studies reported a significant pain reduction between one day and six months after the cryoablation procedure. The highest mean difference between pre- and post-procedure scores was 5.8 (VAS scale) after four weeks. The overall rate of minor and major complications was 12.74%. Cryoablation improved the QoL of cancer patients and decreased the need for analgesics. Authors concluded that cryoablation is a safe and useful procedure for palliating painful bone metastasis and increasing the QoL of cancer patients. Future studies should adopt a standardized pain reporting scale to allow for meta-analysis.

Lung Tumors

Cryosurgical ablation for the treatment of NSCLC has been studied in a limited number of small studies. Moore, et al (2015) conducted a case series involving 47 subjects with NSCLC. The subjects were followed for a minimum of 5 years after treatment with cryoablation. The authors reported that the five-year survival rate was 67.8% ± 15.3, the cancer-specific survival rate at five years was 56.6% ± 16.5, and the five-year progression-free survival rate was 87.9%. The combined local and regional recurrence rate was 36.2%. Major complications were reported in 6.4% of subjects, with two cases of hemoptysis and a prolonged placement of a chest tube requiring mechanical sclerosis in one subject. No deaths occurred in the first 30 days after treatment.

A prospective case series conducted by deBaere et al (2015), assessed 40 patients with 60 treated metastatic lung tumors (3.5cm or less in diameter) from a variety of primary origin. The most common origin was colorectal cancer (40%). Follow-up to 12 months was reported, involving 35 patients (90%). At 12 months, overall local tumor control, including stable disease, partial response, and complete response, was seen in 49 of 52 metastases (94.2%) and 32 of 35 patients (91.4%). Local failure was observed in three of 52 metastases (5.8%) at 6 and 12 months with increasing size of the ablation zone. Tumor diameter was not found to be a significant factor in the rate of tumor progression (p=0.41). Additional new treatments were administered to 15 of the 40 patients (38%) including systemic treatment (chemotherapy: n=7 and immunotherapy: n=1) and other focal therapies for new metastatic disease (n=10), including 6 cryoablation procedures. One-year disease-specific survival and overall survival rates were 100% and 97.5% respectively. Pneumothorax requiring chest tube placement occurred in nine of the 48 procedures (18.8%), and chest tubes were removed after one day (n=8) or two days (n=1). Common Terminology Criteria for Adverse Events (CTCAE) grade 3 adverse events within 30 days of the procedure occurred in three of 48 (6%) procedures including a delayed pneumothorax requiring pleurodesis, a thrombosis of a pre-existing hemodialysis access arterio-venous fistula requiring thrombectomy, and a non-cardiac chest pain that spontaneously resolved. No grade 4 or 5 procedure-related adverse events occurred. No procedural-

related delayed adverse events were observed. The study outcomes were considered interim results at 1-year follow up.

In 2021, deBaere et al published follow-up 5- year results in a prospective, multicenter, single arm study of the 40 patients from the original 2015 study, using a standardized CA protocol (ECLIPSE). The primary end point was local tumor control both per tumor and per patient. Local failure was defined as a greater than 20% increase in diameter of the ablation zone from baseline imaging. Secondary end points included cancer-specific survival, overall survival, and quality of life. The local tumor control rates per index tumor were 87.9% at 3 years and 79.2% at 5 years; the 5-year overall survival was 46.7% with 78.2% of surviving patients without progression. Five treated patients experienced local progression throughout the duration of the study, with a local control rate of treated tumors of 75.0% per patient and 79.2% per tumor when treating lung metastases up to 3.5 cm. The authors concluded that these results indicate that the rates of local tumor control, recurrence, and progression in 5 years of follow-up were similar to or better than those of the studies of each type of treatment modality previously described. Although the quality-of-life data did not reach significance, the authors concluded that CA is an effective means of local tumor control in patients with metastatic lung disease.

In 2020, Callstrom et al assessed the safety and local recurrence-free survival after cryoablation for the treatment of pulmonary metastases in a multicenter, single-arm, phase II study in 128 patients with 224 lung metastases ≤3.5 cm (SOLSTICE). The median tumor size was 1.0 cm. Local recurrence-free response was 85.1% at 12 months and 77.2% at 24 months. Secondary local recurrence-free response after re-treatment with cryoablation for recurrent tumors was 91.1% at 12 months and 84.4% at 24 months. Overall survival at 12 and 24 months was 97.6% and 86.6%, respectively.

For individuals who have an unresectable primary or metastatic lung tumor who receive MWA, the evidence includes a single RCT, retrospective observational studies, and systematic reviews of these studies. The RCT by Macchi et al (2017) MWA compared to RFA for lung tumors in 52 patients with a single tumor up to 5 cm, and up to 5 metastases up to 5 cm in size. However, at baseline, the mean tumor size was 2.21 cm (standard deviation [SD], 0.89) in the MWA group and 1.64 cm (SD, 0.80) in the RFA group. Mortality rates at 6 and 12 months did not differ between groups, and complications were significantly lower in the MWA group. Limitations of this study include its small sample size, lack of reporting on blinding, and relatively short follow-up period (12 months). Results were not reported by tumor size or the number of metastases. Systematic reviews determined that local recurrence rates for MWA and RFA were similar at a range of 9 to 47 months of follow-up. Authors conclude that RFA and MWA were both effective with a high safety profile. Limitations exist within the body of evidence include lack of controlled studies and heterogeneity across studies. The studies did not report enough information to assess the effectiveness or safety of MWA in subgroups based on the presence of multiple tumors or total tumor burden. Therefore, conclusions cannot be drawn about the comparable effectiveness of MWA in patients that have more than one tumor.

Murphy et al (2023) conducted a bi-institutional retrospective cohort study to evaluate the safety and effectiveness of percutaneous imagine-guided thermal ablation (IGTA) for juxtacardiac lung tumors.

The study included 23 consecutive patients with 30 juxtacardiac lung tumors located less than or equal to ten millimeters from the pericardium treated in 28 IGTA sessions (25 sessions of cryoablation and three sessions of microwave ablation). The primary outcome was any adverse cardiac event within 90 days after ablation. Secondary outcomes included noncardiac adverse events, local tumor progression–free survival (LT-PFS), and the cumulative incidence of local tumor progression with death as a competing risk. The median imaging follow-up duration was 22 months. Primary technical success was achieved in 25 (89%) ablations. No adverse cardiac events attributable to IGTA occurred. One patient experienced a phrenic nerve injury. The median LT-PFS duration was 59 months. At one, three, and five years, LT-PFS was 90% (95% CI, 78%–100%), 74% (CI, 53%–100%), and 45% (CI, 20%–97%), respectively, and the cumulative incidence of local tumor progression was 4.3% (CI, 0.29%–19%), 11% (CI, 1.6%–30%), and 26% (CI, 3.3%–58%), respectively.

Breast Tumors

The available literature on the use of cryosurgery in the treatment of breast cancer has shown that complete ablation can be achieved in most cases for variably defined small tumors, but studies have not included control groups or compared outcomes of cryosurgery with alternative strategies for managing similar patients. Therefore, no conclusions can be made on the net health outcome of cryosurgery for breast cancer. For the treatment of fibroadenomas, there is a small body of evidence. This evidence has demonstrated that most fibroadenomas become "nonpalpable" following cryoablation. However, there is a lack of comparative trials. Comparative trials are needed to assess this technology and determine how this approach compares with standard treatments.

Pancreatic Tumors

The available evidence on cryosurgery for pancreatic cancer consists of retrospective case series that used cryosurgery for palliation of inoperable disease and a systematic review of these studies. These studies reported that pain relief was achieved in most cases and that complications such as delayed gastric emptying, are common but the true rate of complications is uncertain. Because these studies did not include control groups or compare outcomes of cryosurgery with alternative strategies for managing similar patients, no conclusions can be made on the net health outcome of cryosurgery for pancreatic cancer.

Other Solid Tumors

The evidence on the use of RFA for malignant solid tumors other than liver, consist of case studies, which have reported only short-term outcomes such as tumor response and immediate tumor control. These studies have not determined RFA's effect on the overall survival and net health benefit of these patients compared to the well-established local and systemic treatments currently available for these tumors. More rigorous scientific reviews, long-term follow-up and randomized prospective trials are needed to help better define the role of RFA in the treatment of other solid tumors.

The current evidence on cryoablation for all other indications consists largely of non-comparative, case series and is insufficient to permit conclusions concerning the effect of cryoablation on health outcomes. The outcomes of these case series are inconclusive due to heterogeneity of the patient

populations studied and to the lack of long-term data on the effectiveness of cryosurgical ablation on overall survival. Most case series report only short-term outcomes such as tumor response in terms of shrinkage and tumor recurrence. Comparative studies with already established treatments, larger numbers of subjects, and longer follow-up are needed.

There are well-established local or systemic treatment options available for each of the malignancies in which MWA has been investigated. Potential advantages of MWA include improved local control and the minimally invasive nature of the modality to preserve normal organ tissue, decrease morbidity, and shorten the length of hospitalization, however there is insufficient evidence and a need for further studies to confirm that MWA does indeed improve health outcomes over other standard treatments in indications other than hepatic and lung tumors.

PROFESSIONAL GUIDELINE(S)

The American College of Gynecology (ACOG) released an updated practice bulletin in mid-2021 stating that laparoscopic RFA can be considered as a minimally invasive treatment option for the management of symptomatic leiomyomas in patients who desire uterine preservation and are counseled about the limited available data on reproductive outcomes.

The American Association of Gynecologic Laparoscopists (AAGL) (2022) commented that current review of the literature suggests RFA offers a safe and effective alternative treatment option for patients with symptomatic fibroids who seek uterine preservation. Although RFA is not yet approved by the FDA as a fertility-enabling treatment, subsequent successful pregnancy outcomes have been reported in the literature. More robust fertility data is required to confirm its safety for those who actively desire future pregnancy.

The Society of Interventional Radiology (2020) published a position statement on the role of percutaneous ablation in renal cell carcinoma. Their relevant recommendations are as follows:

- "In patients with small renal tumors (stage T1a), percutaneous thermal ablation is a safe and effective treatment with fewer complications than nephrectomy and acceptable long-term oncological and survival outcomes. (Level of Evidence: C; Strength of Recommendation: Moderate)"
- "In selected patients with suspected T1a renal cell carcinoma, percutaneous thermal ablation should be offered overactive surveillance. (Level of Evidence: C; Strength of Recommendation: Moderate)"
- "In high-risk patients with T1b renal cell carcinoma who are not surgical candidates, percutaneous thermal ablation may be an appropriate treatment option; however, further research in this area is required. (Level of Evidence: D; Strength of Recommendation: Weak)"
- "Radiofrequency ablation, cryoablation, and microwave ablation are all appropriate modalities for thermal ablation, and method of ablation should be left to the discretion of the operating physician. (Level of Evidence: D; Strength of Recommendation: Weak)"

The 2021 American Urological Association guidelines on Stage I renal masses indicate that cryoablation may be offered as an option for the management of cT1a solid renal masses < 3 cm in size, with the percutaneous technique being preferred over a surgical approach wherever feasible to minimize morbidity (Moderate Recommendation; Evidence Level: Grade C). Counseling about thermal ablation should include information regarding an increased likelihood of tumor persistence or local recurrence after primary thermal ablation relative to surgical excision, which may be addressed with repeat ablation if further intervention is elected. (Strong Recommendation; Evidence Level: Grade B).

The American College of Radiology Appropriateness Criteria (2009, updated 2021) for post-treatment follow-up and active surveillance of renal cell carcinoma (RCC) indicates that "ablative therapies, such as radiofrequency ablation, microwave ablation, and cryoablation, have been shown to be effective and safe alternatives (to surgical resection) for the treatment of small, localized RCCs.

In 2018, The American Association for the study of Liver Disease released guidelines for the diagnosis, staging and management of HCC. The guidelines suggest that patients who do not meet Milan criteria can be treated with ablative therapy to induce tumor death and deter tumor progression beyond the Milan criteria. In regard to the criteria, the association states, “Thermal ablation is superior to ethanol injection. Thermal ablative techniques have the best efficacy in tumors with maximum diameter less than 3 cm, although microwave ablation potentially provides better tumoral response than RFA. Patients that are post-ablation are at high risk for recurrence and surveillance should be performed with contrast-enhanced CT or MRI every 3-6 months”.

NCCN Guidelines for NSCLC V.3.2025 notes that the use of image-guided thermal ablation (IGTA), which includes radiofrequency ablation, microwave ablation, and cryoablation, may be a treatment option for NSCLC. IGTA may be an option for select patients who are deemed “high risk”-those patients with tumors that are for the most part surgically resectable but rendered medically inoperable due to comorbidities. IGTA has been successfully accomplished in patients considered “high risk,” objectively defined with a single major and/or two or more minor criteria. Major criteria for high risk included an FEV1 or DCLO ≤ 50 percent and minor criteria included less depressed FEV1 or DCLO between 51-60 percent, advanced age ≥ 75 years, pulmonary hypertension, VEF ≤ 40 percent, resting or exercise paO2 <55mmHg, and PCO2>45 mmHg.

The NCCN guidelines (V.3.2025) for Kidney Cancer indicate that thermal ablation (eg, cryosurgery, radiofrequency ablation, microwave ablation) is an option for the management of clinical stage T1 renal lesions. Thermal ablation is an option for clinical T1b masses in select patients not eligible for surgery. Biopsy of lesions is recommended to be done prior to or at time of ablation. Ablative techniques may require multiple treatments to achieve the same oncologic outcomes as conventional surgery.

The NCCN guidelines for head and neck cancers (v.3.2025), breast cancer (v.4.2025) bone cancer (v.2.2025), and pancreatic adenocarcinoma (v.2.2025) do not address thermal ablation.

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) has cleared hundreds of 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. 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. FDA product code: GEI.

The Sonata Sonography-Guided Transcervical Fibroid Ablation System (Gynesonics) received FDA clearance for marketing in 2018. This device is intended for diagnostic intrauterine imaging and transcervical treatment of symptomatic uterine fibroids, including those associated with heavy menstrual bleeding.

The RFA system Acessa for uterine fibroids, received FDA clearance for marketing in 2012 (K121858). The next generation of the Acessa System, The Acessa ProVu System, received FDA clearance in 2018.

The United States Food and Drug Administration (FDA) regulates medical devices. All [device] including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2025 Jun 25]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls on our website by the date that the FDA posts the information on our website. Available from: Medical Device Recalls | FDA [accessed 2025 Jun 25]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
19105 (E/I)	Ablation, cryosurgical, of fibroadenoma, including ultrasound guidance, each fibroadenoma
20982	Ablation therapy for reduction or eradiation of one or more bone tumors (e.g., metastasis) including adjacent soft tissue when involved by tumor extension, percutaneous, including imaging guidance when performed; radiofrequency

Code	Description
20983 (E/I)	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; cryoablation
32994	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; cryoablation
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, including imaging guidance when performed, radiofrequency, unilateral
47370	Laparoscopy, surgical, ablation of one or more liver tumor(s); radiofrequency
47380	Ablation, open, of one or more liver tumor(s); radiofrequency
47371 (E/I)	Laparoscopy, surgical ablation of one or more liver tumor(s); cryosurgical
47381 (E/I)	Ablation, open, of one or more liver tumor(s); cryosurgical
47382*	Ablation, one or more liver tumor(s), percutaneous, radiofrequency (*E/I when utilized for Cryosurgical Ablation)
47383 (E/I)	Ablation, 1 or more liver tumor(s), percutaneous, cryoablation
50250	Ablation, open, one or more renal mass lesion(s), cryosurgical, including intraoperative ultrasound guidance and monitoring, if performed
50542	Laparoscopy, surgical; ablation of renal mass lesion(s), including intraoperative ultrasound guidance and monitoring, when performed
50592	Ablation, one or more renal tumor(s), percutaneous, unilateral, radiofrequency
50593	Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy
58674*	Laparoscopy, surgical, ablation of uterine fibroid(s), including intraoperative ultrasound guidance and monitoring, radiofrequency (*E/I when utilized for Microwave Ablation)
60660 (E/I)	Ablation of 1 or more thyroid nodule(s), one lobe or the isthmus, percutaneous, including imaging guidance, radiofrequency (effective 01/01/25)
60661 (E/I)	Ablation of 1 or more thyroid nodule(s), additional lobe, percutaneous, including imaging guidance, radiofrequency (List separately in addition to code for primary procedure) (effective 01/01/25)

Code	Description
60699*	Unlisted procedure, endocrine system (*E/I when used for adrenal or thyroid ablation [RF, CA, or MWA])
76940*****	Ultrasound guidance for, and monitoring of, parenchymal tissue ablation (*E/I when utilized for Microwave Ablation)
77013	Computed tomography guidance for, and monitoring of, parenchymal tissue ablation
77022	Magnetic resonance imaging guidance for, and monitoring of, parenchymal tissue ablation
0581T (E/I)	Ablation, malignant breast tumor(s), percutaneous, cryotherapy, including imaging guidance when performed, unilateral
58580***** Effective 01/01/24 0404T Termed 12/31/23	Transcervical ablation of uterine fibroid(s), including intraoperative ultrasound guidance and monitoring, radiofrequency (Effective 01/01/24) (Replacing 0404T) (*E/I when utilized for CA or MWA) Transcervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency

HCPCS Codes

Code	Description
C2618	Probe/needle, cryoablation
C1886	Catheter, extravascular tissue ablation, any modality (insertable)

ICD10 Codes

Code	Description
Multiple Codes	

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SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Based on our review, there is no specific regional or national coverage determinations addressing Thermal Tumor Ablation other than the national coverage determination for cryosurgery of the prostate which is highlighted in a separate corporate medical policy.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION	
Committee Approval Dates	
07/18/24, 07/17/25	
Date	**Summary of Changes**
07/17/25	• Annual review/immediate approval; new medically appropriate criteria for CA, new medically appropriate statements with MWA, policy criteria deleted resulting in positive change.
01/01/25	• Summary of changes tracking implemented.
11/15/24	• Original effective date