CareSource

# MEDICAL POLICY STATEMENT
# Ohio MyCare

| Policy Name & Number | Date Effective |
|---|---|
| Radiofrequency and Microwave Ablation of Tumors-MyCare OH FIDE-MM-1828 | 01/01/2026 |
| **Policy Type** | |
| **MEDICAL** | |

Medical Policy Statements are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased, or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage or Certificate of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other plan policies and procedures.

Medical Policy Statements do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage or Certificate of Coverage) for the service(s) referenced in the Medical Policy Statement. Except as otherwise required by law, if there is a conflict between the Medical Policy Statement and the plan contract, then the plan contract will be the controlling document used to make the determination.

According to the rules of Mental Health Parity Addiction Equity Act (MHPAEA), coverage for the diagnosis and treatment of a behavioral health disorder will not be subject to any limitations that are less favorable than the limitations that apply to medical conditions as covered under this policy.

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A. Subject

**Radiofrequency and Microwave Ablation of Tumors**

B. Background

Radiofrequency ablation of a tumor involves the delivery of high frequency alternating current to induce thermal injury of targeted tissue. Evidence for the use of radiofrequency ablation is constantly evolving based on the type of tumor and its location.

Hepatocellular carcinoma is the most common type of primary liver cancer. For most patients, treatment with curative intent is not possible. Treatment options include surgical excision, hepatic artery infusion chemotherapy, trans-arterial bland or chemoembolization, selective interstitial radiotherapy (Yttrium 90 microspheres), percutaneous ethanol injection, cryoablation, and thermo-ablation. Liver transplantation for curative intent may be appropriate for some patients. Radiofrequency ablation and microwave ablation, which are types of thermos-ablation, have proven to be effective local therapy techniques with similar results to other treatment options for smaller tumors.

Liver metastases are a common manifestation of many primary cancers. The number, location, size, and patient's general health influence the choice of treatment for liver metastases. Surgical resection with curative intent is ideal, however this applies to a minority of patients. Non-surgical ablative techniques may be used for both curative and palliative intent. This includes systemic chemotherapy, targeted therapy, immunotherapy, external beam radiotherapy, cryoablation, thermo-ablation, arterial embolization techniques, and selective internal radiation therapy.

Lung cancer is one of the most common types of cancer with symptoms often not appearing until advanced disease, causing poor prognosis. Common treatments for primary or metastatic cancer in the lung include surgery, chemotherapy, radiotherapy, photodynamic therapy, thermal ablation, immunotherapy, and biological therapy. Treatment selection is based on type, size, position and stage of cancer, and the patient's overall health.

Microwave ablation (MWA) uses microwave energy to cause thermal coagulation and tissue necrosis at a specific location. When a tumor is not amenable to resection or a patient is ineligible for surgery, MWA may be an appropriate alternative definitive treatment. This procedure can be done percutaneously using minimally invasive surgical techniques, or during open surgery, and involves placement of one more probes directly into the tumor's location, where microwave energy can be directly applied, causing destruction of the tumor and limited surrounding tissues. Microwave ablation does not spare vessels.

C. Definitions

- **Tumor Ablation** – Direct application of energy to eradicate or destroy focal tumors. The method of ablation is dependent on the characteristics of the lesion and risk mitigation.
  - **Microwave Ablation (MWA)** – Delivery of high-frequency microwave energy to rapidly agitate water molecules in the target tissue. The energy is converted to heat, which causes tissue necrosis.
  - **Radiofrequency Ablation (RFA)** – Delivery of radio waves to generate heat and induce tissue destruction in the targeted area.

D. Policy

I. Microwave ablation for tumor treatment using an FDA-approved device is considered medically necessary when **ANY** (either A or B) of the following indications are met:

A. Member has primary or metastatic hepatic (liver) tumor, and **ALL** the following:

1. The tumor is unresectable due to location of lesion(s), or the member has comorbid condition(s) that are contraindicative to surgery.
2. The tumor is at most 5 cm in size, or there are no more than 3 nodules, all of which are no more than 3 cm in size.
3. Microwave ablation may be used alone or in conjunction with open or minimally invasive resection of other liver tumors. Curative resection of all disease must be the stated goal of therapy.

or

B. Member has primary or metastatic lung tumor, and **ALL** the following:

1. The tumor is unresectable due to location of lesion(s), or the member has comorbid condition(s) that are contraindicative to surgery.
2. Single tumor is no more than 3 cm in size.

II. Microwave ablation is not covered for any other indication, including (but not limited to), the following:

A. Microwave ablation for any other tumor type is considered experimental and investigational due to a lack of clinical evidence regarding efficacy.

B. Microwave ablation for tumors larger than 5 cm or more than 3 nodules larger than 3 cm is considered experimental and investigational due to a lack of clinical evidence for efficacy compared to other treatment modalities.

III. Radiofrequency ablation for tumor treatment is considered medically necessary for **ANY** of the following indications:

A. Barrett esophagus with dysplasia

B. bone metastases

C. hepatocellular carcinoma with **ALL** the following:

1. Child-Pugh class A or B liver function (score of 9 or less)
2. surgical evaluation indicates at least one of the following:
   a. patient is a candidate for surgical resection following radiofrequency ablation

b. patient is a candidate for transplant following bridge therapy by radiofrequency ablation
c. patient is not a surgical candidate (or elects against surgery)
d. patient is not a transplant candidate

3. tumor has all the following:
   a. location amenable to percutaneous, minimally invasive or open surgical ablation
   b. margins accessible to ablation
   c. not in close proximity to critical structures (eg, major vessels, major bile ducts, diaphragm, other intra-abdominal organs)
   d. single tumor 5cm or smaller in diameter OR no more than 3 tumors, each of which is 3cm or smaller in diameter
4. no portal hypertension

D. kidney tumor with **ALL** the following:
   1. clinical stage T1 renal lesion
   2. patient is not candidate for or elects against active surveillance
   3. patient is not a surgical candidate (or elects against surgery)
   4. tumor is not a renal angiomyolipoma
E. liver metastases from colorectal carcinoma with **ALL** the following:
   1. patient is not an ideal surgical candidate (or elects against surgery)
   2. tumor has all the following:
      a. location amenable to percutaneous or surgical ablation
      b. margins accessible to ablation
      c. not in close proximity to critical structures (eg, major vessels, major bile ducts, diaphragm, other intra-abdominal organs)
      d. single tumor 5cm or smaller in diameter OR no more than 3 tumors, each of which is 3cm or smaller in diameter
   3. no extrahepatic disease
F. lung cancer (non-small cell [NSCLC]) with **ALL** the following:
   1. patient is not a surgical candidate (or elects against surgery)
   2. tumor with **ALL** the following:
      a. less than 3 cm in diameter
      b. node negative (stage I)
      c. not in close proximity to major pulmonary vessels or esophagus
G. osteoid osteoma
H. soft tissue sarcoma with **at least ONE** of the following:
   1. gastrointestinal stromal tumor with limited progressive disease (ie, appearance of new lesion, increase in tumor size)
   2. soft tissue sarcoma of extremity, superficial trunk, or head/neck, as indicated by both:
      a. synchronous stage IV disease
      b. need for treatment of tumor bulk limited to single organ that is amenable to local therapy, or palliation of disseminated metastases
I. thyroid cancer with **at least ONE** of the following:

1. differentiated thyroid carcinoma (eg, follicular, papillary) with **at least ONE** of the following:
   a. distant metastasis or persistent disease not amenable to treatment with radioactive iodine
   b. recurrent disease following treatment of locoregional disease
2. medullary carcinoma with **at least ONE** of the following:
   a. palliative treatment of symptomatic metastases or progressive disease needed
   b. Patient asymptomatic, with **at least ONE** of the following:
      01. disease metastasis
      02. persistent disease following treatment of locoregional disease
      03. recurrent disease following treatment of locoregional disease

J. thyroid nodules, with **ALL** the following:
1. compressive symptoms from nodules (eg, cough, dysphagia, foreign body sensation, pain, voice changes)
2. patient not a surgical candidate (or elects against surgery)

K. uterine leiomyomas with **ALL** the following:
1. laparoscopic ultrasound-guided procedure planned
2. leiomyomas documented by imaging study (eg, ultrasound) or hysteroscopy
3. patient desires uterine conservation or is not a surgical candidate
4. patient is premenopausal
5. persistent symptoms (3 months or greater in duration) directly attributed to presence of leiomyomas, as indicated by **at least ONE** of the following:
   a. abnormal uterine bleeding unresponsive to conservative management (eg, hormonal therapy)
   b. bowel dysfunction
   c. dyspareunia
   d. infertility
   e. iron deficiency anemia
   f. pelvic pain or pressure
   g. urinary dysfunction
6. testing has ruled out other potential causes of symptoms

## E. Summary of Evidence

In 2012, Guan et al. reported the intermediate-term outcomes of a prospective randomized comparison of patients with small renal tumors (<4cm) who were treated with MWA or partial nephrectomy. 48 patients received MWA and 54 had partial nephrectomy. Patients in the groups were matched for age, sex, American Society of Anesthesiologists score, BMI, and tumors size, and were followed for 32-36 months. Surgical and hospitalization times were comparable between the 2 groups. Estimated blood loss, complication rates, and decline of postoperative renal function were statistically significantly less in the MWA group (p=0.0002, p=0.0187, p=0.0092, respectively). At last follow-up, estimated glomerular filtration rate declines in both groups were similar (p=1.0000). Disease-specific deaths did not occur and overall local

recurrence-free survival by Kaplan-Meier estimates at 3 years were 91.3% for MWA and 96.0% for partial nephrectomy (p=0.5414).

Macchi et al (2017) published results of the LUMIRA controlled prospective multi-center randomized trial for non-small-cell lung cancer, where 52 patients with state IV disease were randomized into a RFA group or a MWA group. The technical and clinical success were measured along with survival and complication rates. For RFA group, there was a significant reduction in tumor size only between 6 and 12 months (p=0.0014). For MWA group, there was a significant reduction in tumor size between 6 and 12 months (p=0.0003) and between pre-therapy and 12 months (p=0.0215). There were no significant differences between the groups in terms of survival time (p=0.883), while the pain level in MWA group was significantly less than in RFA group (1.79 < 3.25, p=0.0043). The authors concluded both RFA and MWA are appropriate choices in terms of efficacy and safety in the treatment of lung tumors. However, MWA produced less intraprocedural pain and a significant reduction in tumor mass compared to RFA.

Glassberg et al (2019) compared microwave ablation (MWA) with hepatic resection (HR) for the treatment of hepatocellular carcinoma and liver metastases in a systematic review and meta-analysis. While HR is the gold standard for liver cancer treatment, few patients are eligible due to comorbidities or tumor location. The authors identified 1 RCT and 15 observational studies which showed an increased local tumor recurrence with MWA versus HR (risk ratio (RR) = 2.49; p = 0.016). and 3-year disease-free survival. In secondary measures, HR provided significantly higher 3- and 5-year overall survival (RR = 0.94; p = 0.03 and RR = 0.88; p = 0.01, respectively), and 3-year disease-free survival (RR = 0.78; p = 0.009). MWA exhibited significantly shorter length of stay (weighted mean difference (WMD) = -6.16 days; p < 0.001) and operative time (WMD = - 58.69 min; p < 0.001), less intraoperative blood loss (WMD = - 189.09mL; p = 0.006), and fewer complications than HR (RR = 0.31; p < 0.001). Glassberg et al. concluded that MWA can be an effective and safe alternative to HR in patients that are not amenable to resection.

The Society of Interventional Radiology released a standards of practice on percutaneous ablation of non-small cell lung cancer and metastatic disease of the lungs (Genshaft et al, 2021). Indirect comparisons from systematic reviews and meta-analyses have found that radiofrequency ablation, cryoablation, and microwave ablation are appropriate for image-guided thermal ablation of lung tumors. The method of ablation should be determined by lesion characteristic and risk mitigation, with discretion left to the operating physician. The Society of Interventional Radiology report that MWA is preferred when tumors are adjacent to the pulmonary vasculature, when patients have a pacemaker, and when pulmonary or pleural hemorrhage is of concern. Genshaft et al. also report that there is insufficient published evidence on use of this technique in tumors larger than 5cm.

The National Comprehensive Cancer Network (NCCN) guidelines for non-small cell lung cancer (2025) recommends image-guided thermal ablation (eg, cryotherapy, microwave,

radiofrequency) as an option for selected patients. Image-guided thermal therapy is considered an option for the management of NSCLC lesions smaller than 3cm. There is also evidence to support ablation of tumors in selected patients with state 1A NSCLC, those who present with multiple lung cancers, or those who present with locoregional recurrence of symptomatic local thoracic disease.

The NCCN guidelines for hepatocellular carcinoma (2025) state that ablation alone may be curative in treating tumors no larger than 3cm. In well-selected patients with multiple small tumors, MWA and RFA ablation may also be considered as definitive treatment in the context of a multidisciplinary review. Tumors 3 to 5cm in size may be treated to prolong survival using arterially directed therapies, or with combination of an arterially directed therapy and ablation as long as tumor location is accessible for ablation. Unresectable or inoperable tumors greater than 5cm in size should utilize arterially directed therapy, systemic therapy, or radiation therapy.

## F. Conditions of Coverage

NA

## G. Related Policies/Rules

NA

## H. Review/Revision History

| | DATE | ACTION |
|---|---|---|
| **Date Issued** | 06/18/2025 | New market, approved at Committee. |
| **Date Revised** | | |
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