MEDICAL POLICY STATEMENT
Ohio Medicaid

Policy Name & Number	Date Effective
Radiofrequency and Microwave Ablation of Tumors-OH MCD-MM-1349	02/01/2023-01/31/2024
Policy Type	
MEDICAL	

Medical Policy Statement prepared by CareSource and its affiliates 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 documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CareSource and its affiliates do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) 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, including 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 includes 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. Tumor is at most 5cm in size OR there are no more than 3 nodules, all of which are no more than 3cm 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 3cm 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 on its efficacy.

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

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

A. Bone metastases;

B. Osteoid osteoma;

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 (e.g., 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 (e.g., 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 3cm in diameter;
      b. Node negative (stage I);
      c. Not in close proximity to major pulmonary vessels or esophagus;
      d. Solitary peripheral lesion;

G. Soft tissue sarcoma with **ALL** the following:
   1. Gastrointestinal stromal tumor with limited progressive disease (i.e., 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;

H. Thyroid cancer with **ALL** the following:
   1. Differentiated thyroid carcinoma (e.g., 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;

I. Uterine leiomyomas with **ALL** the following:
   1. Laparoscopic ultrasound-guided procedure planned;
   2. Leiomyomas documented by imaging study (e.g., ultrasound) or hysteroscopy);
   3. Patient desires uterine conservation;
   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 (e.g., 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 cases of symptoms.

E. Conditions of Coverage

NA

F. Related Policies/Rules

NA

G. Review/Revision History

	DATE	ACTION
Date Issued	10/12/2022	
Date Revised		
Date Effective	02/01/2023	
Date Archived	01/31/2024	This Policy is no longer active and has been archived. Please note that there could be other Policies that may have some of the same rules incorporated and CareSource reserves the right to follow CMS/State/NCCI guidelines without a formal documented Policy.

H. References

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