

Blue Cross Blue Shield of Massachusetts is an Independent Licensee of the Blue Cross and Blue Shield Association

## Medical Policy Microwave Tumor Ablation

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Policy Number: 912

BCBSA Reference Number: 7.01.133 (For Plan internal use only) NCD/LCD: NA

## **Related Policies**

- Cryosurgical Ablation of Miscellaneous Solid Tumors Other Than Liver, Prostate, or Dermatologic Tumors, #<u>260</u>
- Cryosurgical Ablation of Primary or Metastatic Liver Tumors, #633
- Intraoperative Radiation Therapy, #278
- Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors, #259
- Radiofrequency Ablation of Primary or Metastatic Liver Tumors, #286
- Radioembolization for Primary and Metastatic Tumors of the Liver, #292

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## **Policy**

# Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue<sup>SM</sup> and Medicare PPO Blue<sup>SM</sup> Members

Microwave ablation of primary or metastatic hepatic tumors may be considered <u>MEDICALLY</u> <u>NECESSARY</u> under the following conditions:

- The tumor is unresectable due to location of lesion[s] and/or comorbid conditions
- A single tumor of  $\leq 5$  cm or up to 3 nodules  $\leq 3$  cm each.

Microwave ablation of primary or metastatic lung tumors may be considered <u>MEDICALLY</u> <u>NECESSARY</u> under the following conditions:

- The tumor is unresectable due to location of lesion and/or comorbid conditions
- A single tumor of ≤3 cm.

Microwave ablation of more than a single primary or metastatic tumor in the lung is considered **INVESTIGATIONAL**.

Microwave ablation of primary or metastatic tumors other than liver or lung is considered **INVESTIGATIONAL**.

## **Prior Authorization Information**

#### Inpatient

 For services described in this policy, precertification/preauthorization <u>IS REQUIRED</u> for all products if the procedure is performed <u>inpatient</u>.

### Outpatient

• For services described in this policy, see below for products where prior authorization <u>might be</u> <u>required</u> if the procedure is performed <u>outpatient</u>.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is <b>not required</b> .
Commercial PPO and Indemnity	Prior authorization is <b>not required</b> .
Medicare HMO Blue <sup>s</sup> <sup>™</sup>	Prior authorization is <b>not required</b> .
Medicare PPO Blue <sup>SM</sup>	Prior authorization is <b>not required</b> .

## CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

## **CPT Codes**

There is no specific CPT code for microwave ablation.

## DESCRIPTION

#### **Microwave Ablation**

Microwave ablation (MWA) uses microwave energy to induce an ultra-high-speed, 915 MHz or 2 450 MHz (2.45 GHz), alternating electric field, which causes water molecule rotation and creates heat. This results in thermal coagulation and localized tissue necrosis. In MWA, a single microwave antenna or multiple antennas connected to a generator are inserted directly into the tumor or tissue to be ablated; energy from the antennas generates friction and heat. The local heat coagulates the tissue adjacent to the probe, resulting in a small, 2 cm to 3 cm elliptical area (5'3 cm) of tissue ablation. In tumors greater than 2 cm in diameter, 2 to 3 antennas may be used simultaneously to increase the targeted area of MWA and shorten the operative time. Multiple antennas may also be used simultaneously to ablate multiple tumors. Tissue ablation occurs quickly, within 1 minute after a pulse of energy, and multiple pulses may be delivered within a treatment session, depending on tumor size. The cells killed by MWA are typically not removed but are gradually replaced by fibrosis and scar tissue. If there is a local recurrence, it occurs at the margins. Treatment may be repeated as needed. Microwave ablation may be used for the following purposes: (1) to control local tumor growth and prevent recurrence; (2) to palliate symptoms; and (3) to prolong survival.

Microwave ablation is similar to radiofrequency (RFA) and cryosurgical ablation. However, MWA has potential advantages over RFA and cryosurgical ablation. In MWA, the heating process is active, which produces higher temperatures than the passive heating of RFA and should allow for more complete thermal ablation in less time. The higher temperatures reached with MWA (>100°C) can overcome the "heat sink" effect 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 and does not require grounding pads, 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. Finally, MWA can take 20% to 30% less time than RFA, because multiple antennas can be used simultaneously

for multiple ablations. There is no comparable RFA system with the capacity to drive multiple electrically dependent electrodes.

#### **Adverse Events**

Complications from MWA may include pain and fever. Other complications associated with MWA include those caused by heat damage to normal tissue adjacent to the tumor (eg, intestinal damage during MWA of the kidney or liver), structural damage along the probe track (eg, pneumothorax as a consequence of procedures on the lung), liver enzyme elevation, liver abscess, ascites, pleural effusion, diaphragm injury, or secondary tumors if cells seed during probe removal. Microwave ablation should be avoided in pregnant women because potential risks to the patient and/or fetus have not been established, and in patients with implanted electronic devices (eg, implantable pacemakers) that may be adversely affected by microwave power output.

#### Applications

Microwave ablation was first used percutaneously in 1986 as an adjunct to liver biopsy. Since then, MWA has been used to ablate tumors and tissue to treat many conditions including 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. Well-established local or systemic treatment alternatives are available for each of these malignancies. The potential advantages of MWA for these cancers include improved local control and other advantages common to any minimally invasive procedure (eg, preserving normal organ tissue, decreasing morbidity, shortening length of hospitalization). Microwave ablation also has been investigated as a treatment for unresectable hepatic tumors, as both primary and palliative treatment, and as a bridge to a liver transplant. In the latter setting, MWA is being assessed to determine whether it can reduce the incidence of tumor progression while awaiting transplantation and thus maintain a patient's candidacy while awaiting a liver transplant.

### **Summary**

Microwave ablation (MWA) is a technique to destroy tumors and soft tissue using microwave energy to create thermal coagulation and localized tissue necrosis. Microwave ablation is used to treat tumors not amenable to resection and to treat patient's ineligible for surgery due to age, comorbidities, or poor general health. Microwave ablation may be performed as an open procedure, laparoscopically, percutaneously, or thoracoscopically under image guidance (eg, ultrasound, computed tomography, magnetic resonance imaging) with sedation, or local or general anesthesia. This technique is also referred to as microwave coagulation therapy.

For individuals who have an unresectable primary or metastatic hepatic tumor who receive microwave ablation (MWA), the evidence includes randomized controlled trials (RCTs), comparative observational studies, and systematic reviews comparing MWA to radiofrequency ablation (RFA) and to surgical resection. Relevant outcomes are overall survival (OS), disease-specific survival, symptoms, quality of life (QOL), and treatment-related mortality and morbidity. The body of evidence indicates that MWA is an effective option in patients for whom resection is not an option. Although studies had methodological limitations, results consistently showed that that MWA and RFA had similar survival outcomes with up to 5 years of follow-up in patients with a single tumor <5 cm or up to 3 nodules <3 cm each. In a meta-analysis of observational studies, patients receiving MWA had higher local recurrence rates and lower survival than those who received resection, but the patient populations were not limited to those who had unresectable tumors. Microwave ablation was associated with lower complications, intraoperative blood loss, and hospital length of stay. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

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. Relevant outcomes are OS, disease-specific survival, symptoms, QOL, and treatment-related mortality and morbidity. The body of evidence indicates that MWA is an effective option in patients for whom resection is not an option. In the RCT, direct comparison of MWA and RFA in patients with primary

or metastatic lung cancer (mean tumor size, 1.90 cm [ $\pm$  0.89] at baseline) found similar mortality rates up to 12 months of follow-up. In the first of 3 systematic reviews that included 12 retrospective observational studies, local recurrence rates were similar for MWA and RFA at a range of 9 to 47 months of follow-up. In the second systematic review with a meta-analysis, there was lower OS with MWA compared to RFA but studies were not directly comparable due to clinical and methodological heterogeneity. However, the authors concluded that percutaneous RFA and MWA were both effective with a high safety profile. In the third systematic review using a network meta-analysis, the weighted average OS rates for MWA were 82.5%, 54.6%, 35.7%, 29.6%, and 16.6% at 1, 2, 3, 4, and 5 years, respectively. Limitations of the body of evidence included a lack of controlled studies and heterogeneity across studies. The RCT did not report results by tumor size or the number of metastases. The observational studies included in the systematic reviews did not report sufficient information to assess the effectiveness or safety of MWA in subgroups based on the presence of multiple tumors or total tumor burden. Therefore, conclusions about the evidence sufficiency can only be made about patients with single tumors. For this population, the evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have an unresectable primary or metastatic renal tumor who receive MWA, the evidence includes a single RCT that compared MWA to partial nephrectomy, retrospective reviews, systematic reviews, and meta-analyses of the retrospective reviews (with or without the single RCT) and case series. Relevant outcomes are OS, disease-specific survival, symptoms, QOL, and treatment-related mortality and morbidity. In the RCT, overall local recurrence-free survival at 3 years was 91.3% for MWA and 96.0% for partial nephrectomy (p=.54). This positive outcome should be replicated in additional RCTs. There are also no controlled studies comparing MWA to other ablation techniques in patients with renal tumors. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have unresectable primary or metastatic solid tumors other than hepatic, lung, or renal who receive MWA, the evidence includes systematic reviews and case series. Relevant outcomes are OS, disease-specific survival, symptoms, QOL, and treatment-related mortality and morbidity. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Date	Action
12/2023	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
12/2022	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
12/2021	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
12/2020	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
2/2020	Policy statements changed to medically necessary for lung and liver tumors; statements for other tumor types unchanged. Effective 2/1/2020
10/2018	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
1/2018	Clarified coding information.
10/2017	Annual policy review. New references added.
4/2016	Annual policy review. New references added.
12/2014	Annual policy review. New references added.
1/2014	Annual policy review. New references added.
4/2013	Annual policy review. New references added.
2/2013	New policy describing non-coverage.

## **Policy History**

## Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information: <u>Medical Policy Terms of Use</u> <u>Managed Care Guidelines</u> <u>Indemnity/PPO Guidelines</u> <u>Clinical Exception Process</u> <u>Medical Technology Assessment Guidelines</u>

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