BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Microwave Tumor Ablation

Policy #: 512
Latest Review Date: October 2024
Category: Surgery

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials. NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **microwave ablation** as a **covered benefit** for patients with one of the following indications:

- Hepatocellular carcinoma (HCC)
- Metastatic liver carcinoma
- Primary or metastatic lung tumors

Blue Advantage will treat **microwave ablation of primary and metastatic tumors, other than those listed above,** as a **non-covered service** and as **investigational.**

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

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 patients 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.

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 potential complications associated with MWA include those caused by heat damage to normal tissue adjacent to the tumor (e.g., intestinal damage during MWA of the kidney or liver), structural damage along the probe track (e.g., 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. MWA should be avoided in pregnant patients since potential risks to the patient and/or fetus have not been established and in patients with implanted electronic devices such as implantable pacemakers that may be adversely affected by microwave power output.

Applications
MWA was first used percutaneously in 1986 as an adjunct to liver biopsy. Since that time, MWA has been used for ablation of tumors and tissue for the treatment of many conditions including: hepatocellular carcinoma, 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 hypothesized advantages of MWA for these cancers include improved local control and those common to any minimally invasive procedure (e.g., preserving normal organ tissue, decreasing morbidity, decreasing length of hospitalization). MWA has been investigated as a treatment for unresectable hepatic tumors, both as primary treatment, palliative treatment and as a bridge to liver transplant. In the latter setting, it is thought that MWA will reduce the incidence of tumor progression while awaiting transplantation and thus maintain a patient's candidacy for liver transplant.

KEY POINTS:
The most recent literature update was performed through August 13, 2024.

Summary of Evidence
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 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 [± 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. No RCTs on the use of MWA for other tumors or conditions were identified. 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.

Practice Guidelines and Position Statements
American College of Chest Physicians
The American College of Chest Physicians (2013) evidence-based guidelines on the treatment of NSCLC noted that the role of ablative therapies in the treatment of high-risk patients with stage I NSCLC is evolving. The guidelines deal mostly with radiofrequency ablation.

American Urological Association
The American Urological Association (2021) updated its guidelines on renal mass and localized renal cancer, which note that both RFA and cryoablation may be offered as options for patients who elect thermal ablation (Conditional Recommendation; Evidence Level: Grade C). Thermal ablation can be considered as an alternate approach in the management of T1a solid renal masses <3 cm. In these patients, a percutaneous technique is preferred (Moderate Recommendation; Evidence Level: Grade C). The guidelines do not specifically address MWA.

National Comprehensive Cancer Network
The National Comprehensive Cancer Network (NCCN) guidelines on hepatocellular carcinoma (HCC) (v.2. 2024) lists MWA (along with radiofrequency ablation, cryoablation and percutaneous alcohol injection) as a treatment option for HCC tumors in patients who are not candidates for potential curative treatments (e.g., resection and transplantation) and do not have large-volume extrahepatic disease. Ablation should only be considered when tumors are accessible by percutaneous, laparoscopic or open approaches. The guidelines indicate " Ablation alone may be curative in treating tumors less than or equal to 3 cm [...] Lesions 3 to 5 cm 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."

The guidelines on non-small cell lung cancer (NSCLC) (v.7.2024) state that image-guided thermal ablation therapies such as cryotherapy, microwave, or radiofrequency may be an option for select medically inoperable patients not receiving stereotactic ablative radiotherapy or definitive radiotherapy. Image-guided thermal ablation therapy is considered an option for the management of NSCLC lesions <3 cm. as Ablation for NSCLC lesions >3 cm has been associated with higher rates of local recurrence and complications.

Guidelines on small-cell lung cancer (v.3.2024) state that stereotactic ablative radiotherapy is an option for certain patients with medically inoperable stage I to IIA small-cell lung cancer.

The Network guidelines on neuroendocrine tumors (v.2.2024) state that cytoreductive surgery or ablative therapies (eg, radiofrequency, cryotherapy, microwave) may be considered in patients with progressive hepatic-predominant metastatic disease to reduce tumor bulk and relieve symptoms of hormone hypersecretion (category 2B). Additionally, although prospective data for

ablative therapy interventions are limited, the guideline notes that "percutaneous thermal ablation, often using microwave energy, can be considered for oligometastatic liver disease, generally up to 4 lesions each smaller than 3 cm.

The guidelines on kidney cancer (v.1.2025) do not specifically address the role of MWA, but state that other thermal ablation techniques (RFA and cryotherapy) may be an option for T1 renal lesions, particularly for masses <3 cm.

The guidelines on breast cancer (v.4.2024) do not address thermal ablation techniques such as MWA.

Thyroid cancer guidelines from NCCN (v.3.2024) recommend ablation techniques such as cryoablation or RFA as an option for metastatic disease in select patients. There is not specific mention of MWA.

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (2016) updated its guidance on MWA for treatment of metastases in the liver. The revised guidance states:

- Current evidence on MWA for treating liver metastases raises no major safety concerns and the evidence on efficacy is adequate in terms of tumor ablation. Therefore, this procedure may be used provided that standard arrangements are in place for clinical governance, consent and audit.
- Patient selection should be carried out by a hepatobiliary cancer multidisciplinary team.
- Further research would be useful for guiding selection of patients for this procedure. This should document the site and type of the primary tumor being treated, the intention of treatment (palliative or curative), imaging techniques used to assess the efficacy of the procedure, long-term outcomes and survival.

The Institute also published guidance on MWA for HCC in 2007. This guidance indicated: “Current evidence on the safety and efficacy of MWA of hepatocellular carcinoma appears adequate to support the use of this procedure provided that the normal arrangements are in place for consent, audit and clinical governance.” The guidance also stated there are no major concerns about the efficacy of MWA, but noted that limited, long-term survival data are available.

The Institute (2022) has published guidance on MWA for lung tumors as well. This guidance indicated that "Evidence on the safety of microwave ablation for treating primary lung cancer and metastases in the lung is adequate but shows it can cause infrequent serious complications. Evidence on its efficacy shows it reduces tumour size. But the evidence on improvement in survival, long-term outcomes and quality of life is limited in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research." The guidance encourages further research.

Society of American Gastrointestinal and Endoscopic Surgeons

In 2023, the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) and the Americas Heapto-Pancreato-Biliary Association (AHPBA) published guidelines for the use of MWA and RFA for the treatment of HCC. The panel recommended that MWA or RFA can be

utilized in patients with HCC and colorectal liver metastases. However, they did note that available evidence was poor quality and treatment decisions should be individualized.

U.S. Preventive Services Task Force Recommendations
Microwave tumor ablation is not a preventive service.

KEY WORDS:

Microwave tumor ablation, Microwave coagulation therapy, Tumor microwave ablation, MWA, breast microwave ablation, breast tumor, metastatic tumors, microwave coagulation therapy, primary tumors, pulmonary microwave ablation, pulmonary tumor, renal microwave ablation, renal tumor, secondary tumors, tumor microwave ablation, urinary system microwave ablation

APPROVED BY GOVERNING BODIES:

Multiple MWA devices have been cleared for marketing by the U.S. Food and Drug Administration 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. Table 1 is a summary of selected MWA devices cleared by FDA.

The Food and Drug Administration used determinations of substantial equivalence to existing radiofrequency and MWA devices to clear these devices.

This evidence review does not address MWA for the treatment of splenomegaly or ulcers for cardiac applications, or as a surgical coagulation tool.

Table 1. Selected Microwave Ablation Devices Cleared by FDA

Device	Indication	Manufacturer	Date Cleared	510(k) No
MedWaves Microwave Coagulation/ Ablation System	General surgery use in open procedures for the coagulation and ablation of soft tissues	MedWaves Incorporated	12/2007	K070356

Acculis Accu2i pMTA Microwave Tissue Ablation Applicator Acculis Accu2i pMTA Applicator and SulisV pMTA Generator	Intraoperative coagulation of soft tissue Software addition	Microsoulis Holdings, Ltd	8/2010 11/2012	K094021 K122762
MicroThermX Microwave Ablation System	Coagulation (ablation) of soft tissue. May be used in open surgical as well as percutaneous ablation procedures.	BSD Medical Corporation	8/2010	K100786

Emprint™ Ablation System Emprint™ Ablation System Emprint™ SX Ablation Platform with Thermosphere™ Technology Emprint™ Ablation Platform with Thermosphere™ Technology and Emprint ™ SX Ablation Platform with Thermosphere™ Technology	Percutaneous, laparoscopic, and intraoperative coagulation (ablation) of soft tissue, including partial or complete ablation of non-resectable liver tumors. Same with design modification of device antenna for percutaneous use 3-D navigation feature assists in the placement of antenna using real-time image guidance during intraoperative and laparoscopic ablation procedures. Antenna modification and update to instructions for use	Medtronic	4/2014 12/2016 9/2017 2/2020	K133821 K163105 K171358 K193232

Certus 140 2.45 GHz Ablation System and Accessories Certus 140™ 2.45 GHz Ablation System and Accessories CertuSurg^{GT} Surgical Tool Certus 140™ 2.45 GHz Ablation System and Accessories Certus 140 2.45GHz Ablation System	Ablation (coagulation) of soft tissue. Ablation (coagulation) of soft tissue in percutaneous, open surgical and in conjunction with laparoscopic surgical settings. Surgical coagulation (including Planar Coagulation) in open surgical settings. Same indication with probe redesign Ablation (coagulation) of soft tissue in percutaneous, open surgical and in conjunction with laparoscopic surgical settings, including the partial or complete ablation of nonresectable liver tumors.	Johnson & Johnson	10/2010 01/2012 7/2013 5/2016 10/2018	K100744 K113237 K130399 K160936 K173756
NEUWAVE Flex Microwave Ablation System (FLEX)	Ablation (coagulation) of soft tissue. Design evolution of Certus 140 2.45GHz Ablation System (K160936)	Johnson & Johnson	3/2017	K163118
Solero Microwave Tissue Ablation (MTA) System and Accessories	Ablation of soft tissue during open procedures	Angiodynamics, Inc.	5/2017	K162449

Microwave Ablation System	Coagulation (ablation) of soft tissue	Surgnova Healthcare Technologies (Zhejiang) Co., Ltd	7/2019	K183153
NEUWAVE Microwave Ablation System and Accessories	Ablation (coagulation) of soft tissue in percutaneous, open surgical and in conjunction with laparoscopic surgical settings, including the partial or complete ablation of non-resectable liver tumors; not intended for use in cardiac procedures.	Johnson & Johnson	11/2020	K200081
IntelliBlate Microwave Ablation System	Coagulation (ablation) of soft tissue	Varian MedicalSystems, Inc	7/2024	K240480

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group-specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT Codes:

As of 01/01/2018, there are no specific CPT codes for microwave ablation.

The unlisted CPT code for the anatomic area should be reported such as code 47399- unlisted procedure liver; 53899- unlisted procedure urinary system (for renal tumors); 32999- unlisted procedure lung; 19499- unlisted procedure breast.

This procedure may also be billed with radiofrequency ablation codes for the anatomic area, such as code 32998- pulmonary, 47382- liver, and 50592- renal.

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POLICY HISTORY:

Adopted for Blue Advantage, October 2012
Available for comment October 24 through December 10, 2012
Medical Policy Group, June 2013
Medical Policy Group, October 2013
Medical Policy Group, January 2015
Medical Policy Group, March 2016
Medical Policy Group, September 2017
Medical Policy Group, December 2017
Medical Policy Group, September 2018: Updates to Key Points and Governing Bodies. No change to policy statement.
Medical Policy Group, October 2019. Available for comment October 4 through November 18, 2019
Medical Policy Group, September 2020
Medical Policy Group, October 2020
Medical Policy Group, October 2021
Medical Policy Group, November 2022
Medical Policy Group, October 2023
UM Committee, December 2023: Policy approved by UM Committee for use for Blue Advantage business.
Medical Policy Group, October 2024

services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.