BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Microwave Tumor Ablation

Policy #: 512
Category: Surgery

Latest Review Date: October 2019
Policy Grade: B

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:

Effective for dates of service on or after December 11, 2012:

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 **noncovered 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 by using microwave energy to create thermal coagulation and localized tissue necrosis. MWA is used to treat tumors considered to be inoperable, not amenable to resection, or to treat patients ineligible for surgery due to age, presence of comorbidities, or poor general health. MWA may be performed as an open procedure, laparoscopically, percutaneously or thoracoscopically under image guidance (e.g., ultrasound, computed tomography [CT] or magnetic resonance imaging [MRI]) with sedation, or local or general anesthesia. This technique may also be referred to as microwave coagulation therapy.

Microwave ablation (MWA) uses microwave energy induces an ultra-high speed, 915 MHz or 2450 MHz (2.45GHz), alternating electric field which causes water molecule rotation and the creation of 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, approximately 2-3 cm elliptical area (5 x 3 cm) of tissue ablation. In tumors greater than 2 cm in diameter, 2-3 antennas may be used simultaneously to increase the targeted area of MWA and shorten operative time. Multiple antennas may also be used simultaneously to ablate multiple tumors. Tissue ablation occurs quickly, within one minute after a pulse of energy, and multiple pulses may be delivered within a treatment session depending on the size of the tumor. The cells killed by MWA are typically not removed but are gradually replaced by fibrosis and scar tissue. If there is local recurrence, it occurs at the edges. Treatment may be repeated as needed. MWA may be used to:

1) control local tumor growth and prevent recurrence; 2) palliate symptoms; and 3) extend survival duration.

MWA is an ablative technique similar to radiofrequency or cryosurgical ablation. However, MWA has some potential advantages over radiofrequency or cryosurgical ablation. In MWA, the heating process is active, which produces higher temperatures than the passive heating of radiofrequency ablation and should allow for more complete thermal ablation in a shorter period of time. The higher temperatures reached with MWA (over 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. MWA does not rely on the conduction of electricity for heating, and therefore, does not have electrical current flow through patients and does not require grounding pads be used during the procedure since there is no risk of skin burns. Additionally, MWA does not produce electric noise, which allows ultrasound guidance to occur during the procedure without interference, unlike radiofrequency ablation. Finally, MWA can be completed in less time than radiofrequency ablation since multiple antennas can be used simultaneously.

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 July 31, 2019.

SUMMARY OF EVIDENCE

For individuals who have unresectable primary or metastatic breast cancer who receive MWA, the evidence includes case series and a systematic review of feasibility and pilot studies conducted prior to 2010. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have an unresectable primary or metastatic hepatic tumor who receive MWA, the evidence includes RCTs, comparative observational studies, case series, and systematic reviews comparing MWA to RFA and to surgical resection. Relevant outcomes are overall survival, disease-specific survival, symptoms, quality of life, 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, they consistently showed that that MWA and RFA had similar survival outcomes with up to 5 years of followup in patients with a single tumor <5 cm or up to 3 nodules <3 cm each. In meta-analyses 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. MWA was associated with lower complications, intraoperative blood loss, and hospital length of stay. The evidence is sufficient to determine the effects of the technology on health outcomes.

For individuals who have an unresectable primary or metastatic lung tumor who receive MWA, the evidence includes one RCT, retrospective observational studies, and systematic reviews of these studies. Relevant outcomes are overall survival, disease-specific survival, symptoms, quality of life, 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 three 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 overall survival 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 overall survival 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 number of metastases. The observational studies included in the systematic reviews did not report sufficient information to assess 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 the effects of the technology on health outcomes.

For individuals who have an unresectable primary or metastatic renal tumor who receive MWA, the evidence includes one RCT that compared MWA to partial nephrectomy, and case series. Relevant outcomes are overall survival, disease-specific survival, symptoms, quality of life, 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=0.54). 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 the effects of the technology on health outcomes.

For individuals who have unresectable primary or metastatic solid tumors other than breast, hepatic, lung, or renal who receive MWA, the evidence includes case series. The evidence is insufficient to determine the effects of the technology on health outcomes.

PRACTICE GUIDELINES AND POSITION STATEMENTS

NCCN

The National Comprehensive Cancer Network (NCCN) guidelines on hepatobiliary cancers (v.3. 2019) lists MWA (along with radiofrequency ablation, cryoablation and percutaneous alcohol injection) as a treatment option for hepatocellular carcinoma 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 “ablative therapies are most effective for [HCC] tumors less than 3 cm…”. Hepatocellular carcinoma tumors between three to five centimeters may also be treated with ablation to prolong survival when used in combination with arterial embolization. Additionally, the tumor location must be accessible to permit ablation of the tumor and tumor margins without ablating major vessels, bile ducts, the diaphragm or other abdominal organs.However, only 1 RCT of MWA compared to RFA was cited in the guidelines to support recommendations for MWA. .

The guidelines on non-small cell lung cancer (v.6.2019) do not mention MWA and state, "for medically operative disease, resection is the preferred local treatment modality (other modalities include SABR, thermal ablation such as radiofrequency ablation,and cryotherapy"). Guidelines on small-cell lung cancer v.2.2019) state, "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.1.2019) state that: “Cytoreductive surgery or ablative therapies (including radiofrequency, microwave, and cryotherapy) may be considered if near-complete treatment of tumor burden can be achieved (category 2B). For unresectable liver metastases, hepatic regional therapy (arterial embolization, chemoembolization, or radioembolization [category 2B]) is recommended.”

NICE

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 microwave ablation for treating liver metastases raises no major safety concerns and the evidence on efficacy is adequate in terms of tumour 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 tumour 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 microwave ablation 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.

American College of Chest Physicians
The 2013 American College of Chest Physicians (ACCP) evidence-based guidelines on the treatment of non-small cell lung cancer note 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.

U.S. PREVENTITIVE 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 devices have been cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process for MWA. The indications for use are labeled for soft tissue ablation, including partial or complete ablation of nonresectable liver tumors. Some devices are cleared for use in open surgical, 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, ulcers, or 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
VivaWave™ Microwave Ablation System	Coagulation of soft tissue Probe modification	Vivant Medical, Inc. ValleyLab	6/2002 4/2006	K011676 K053535
Microsoulis Tissue Ablation System	Intraoperative coagulation of soft tissue	Microsoulis Americas, Inc	1/2006	K052919
MicroSurgeon Microwave Soft Tissue Ablation MTAD-100 MTD-200	Surgical ablation of soft tissue Probe/design modifcations	MicroSurgeon, Inc.	8/2007 2/2009	K070023 K082565
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.Mmay be used in open surgical as well as percutaneous ablation procedures.	BSD Medical Corporation	8/2010	K100786
EmprintTM Ablation System EmprintTM Ablation System Emprint™ SX Ablation Platform with	percutaneous, laparoscopic, and intraoperative coagulation (ablation) of soft	Covidien LLC	4/2014 12/2016 9/2017	K133821 K163105 K171358

Thermosphere™ Technology	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.			
Certus 140 2.45 GHz Ablation System and Accessories Certus 140™ 2.45 GHz Ablation System and Accessories CertuSurgGT 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	NeuWave Medical, Inc.	10/2010 01/2012 7/2013 5/2016 10/2018	K100744 K113237 K130399 K160936 K173756

	percutaneous, open surgical and in conjunction with laparoscopic surgical settings, including the partial or complete ablation of nonresectable liver tumors.			
NEUWAVE Flex Microwave Ablation System (FLEX)	Ablation (coagulation) of soft tissue. Design evolution of Certus 140 2.45GHz Ablation System (K160936)	NeuWave Medical, Inc.	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

BENEFIT APPLICATION: Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.
ITS: Home Policy provisions apply.
FEP: Special benefit consideration may apply. Refer to member's benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

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.

PREVIOUS CODING:
0301T-Destruction/reduction of malignant breast tumor with externally applied focused microwave, including interstitial placement of disposable catheter with combined temperature monitoring probe and microwave focusing sensocatheter under ultrasound thermotherapy guidance. **(Deleted 12/31/2017)**

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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
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Medical Policy Group, September 2017
Medical Policy Group, December 2017
Medical Policy Group, September 2018 **(4)**: Updates to Key Points and Governing Bodies. No change to policy statement.
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