Protocol

Microwave Tumor Ablation

(701133)

Medical Benefit		**Effective Date**: 04/01/20	**Next Review Date**: 01/21
Preauthorization	No	**Review Dates**: 05/13, 05/14, 01/15, 01/16, 01/17, 01/18, 01/19, 01/20	

Preauthorization is not required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: • With an unresectable primary or metastatic solid tumor (e.g., breast, hepatic [primary or metastatic], pulmonary, renal)	Interventions of interest are: • Microwave ablation	Comparators of interest are: • Radiofrequency ablation • Transcatheter arterial chemoembolization • Cryoablation	Relevant outcomes include: • Overall survival • Disease-specific survival • Symptoms • Quality of life • Treatment-related mortality • Treatment-related morbidity
Individuals: • With an unresectable primary or metastatic solid tumor other than breast, liver, lung, or renal	Interventions of interest are: • Microwave ablation	Comparators of interest are: • Radiofrequency ablation • Transcatheter arterial chemoembolization • Cryoablation	Relevant outcomes include: • Overall survival • Disease-specific survival • Symptoms • Quality of life • Treatment-related mortality • Treatment-related morbidity

DESCRIPTION

Microwave ablation (MWA) is a technique to destroy tumors and soft tissue using microwave energy to create thermal coagulation and localized tissue necrosis. MWA is used to treat tumors not amenable to resection and to treat patients ineligible for surgery due to age, 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, magnetic resonance imaging) with sedation, or local or general anesthesia. This technique is also referred to as microwave coagulation therapy.

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 randomized controlled trials (RCTs), comparative observational studies, case series, 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, 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 five years of follow-up in patients with a single tumor less than five cm or up to three nodules less than three 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 OS, 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 nine 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 one, two, three, four, and five 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 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 OS, disease-specific survival, symptoms, quality of life, and treatment-related mortality and morbidity. In the RCT, overall local recurrence-free survival at three 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.

POLICY

Microwave ablation of primary or metastatic hepatic tumors may be considered **medically necessary** under the following conditions:

- The tumor is unresectable due to location of lesion(s) and/or comorbid conditions
- A single tumor of ≤5 cm or up to three nodules less than 3 cm each

Microwave ablation of primary or metastatic lung tumors may be considered **medically necessary** 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 and metastatic tumors other than liver or lung is considered **investigational**.

BACKGROUND

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, two to three 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 one 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. MWA 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.

MWA 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. MWA 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 less time than RFA, because multiple antennas can be used simultaneously.

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 (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 women because potential risks to the patient and/or fetus have not been established, and in patients with implanted electronic devices (e.g., 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 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 (e.g., preserving normal organ tissue, decreasing morbidity, shortening length of hospitalization). MWA 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.

REGULATORY STATUS

Multiple devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) 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 the FDA.

The FDA used determinations of substantial equivalence to existing radiofrequency and MWA devices to clear these devices. FDA product code: NEY.

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	Vivant Medical, Inc.	6/2002	K011676
	Probe modification	ValleyLab	4/2006	K053535
Microsoulis Tissue Ablation System	Intraoperative coagulation of soft tissue	Microsoulis Americas, Inc.	1/2006	K052919
MicroSurgeon Microwave Soft Tissue Ablation	Surgical ablation of soft tissue	MicroSurgeon, Inc.	8/2007	K070023
MTAD-100				
MTD-200	Probe/design modifcations		2/2009	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	Intraoperative coagulation of soft tissue	Microsoulis Holdings, Ltd	8/2010	K094021
Acculis Accu2i pMTA Applicator and SulisV pMTA Generator	Software addition		11/2012	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
EmprintTM Ablation System	Percutaneous, laparoscopic, and intraoperative coagulation (ablation) of soft tissue, including partial or complete ablation of non-resectable liver tumors.	Covidien LLC	4/2014	K133821

Device	Indication	Manufacturer	Date Cleared	510(k) No.
EmprintTM Ablation System	Same with design modification of device antenna for percutaneous use		12/2016	K163105
Emprint™ SX Ablation Platform with Thermosphere™ Technology	3-D navigation feature assists in the placement of antenna using real-time image guidance during intraoperative and laparoscopic ablation procedures.		9/2017	K171358
Certus 140 2.45 GHz Ablation System and Accessories	Ablation (coagulation) of soft tissue.	NeuWave Medical, Inc.	10/2010	K100744
Certus 140™ 2.45 GHz Ablation System and Accessories	Ablation (coagulation) of soft tissue in percutaneous, open surgical and in conjunction with laparoscopic surgical settings.		01/2012	K113237
CertuSurgGT Surgical Tool	Surgical coagulation (including Planar Coagulation) in open surgical settings.		7/2013	K130399
Certus 140™ 2.45 GHz Ablation System and Accessories	Same indication with probe redesign		5/2016	K160936
Certus 140 2.45GHz Ablation System	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.		10/2018	K173756
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

FDA: Food and Drug Administration.

RELATED PROTOCOLS

Cryosurgical Ablation of Miscellaneous Solid Tumors Other Than Liver, Prostate, or Dermatologic Tumors

Cryosurgical Ablation of Primary or Metastatic Liver Tumors

Radioembolization for Primary and Metastatic Tumors of the Liver

Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors

Radiofrequency Ablation of Primary or Metastatic Liver Tumors

Transcatheter Arterial Chemoembolization to Treat Primary or Metastatic Liver Malignancies

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

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We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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