



FEP Medical Policy Manual

FEP 7.01.133 Microwave Tumor Ablation

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Related Policies:

- 7.01.75 - Cryosurgical Ablation of Primary or Metastatic Liver Tumors
- 7.01.91 - Radiofrequency Ablation of Primary or Metastatic Liver Tumors
- 7.01.92 - Cryoablation of Tumors Located in the Kidney, Lung, Breast, Pancreas, or Bone
- 7.01.95 - Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors
- 8.01.11 - Transcatheter Arterial Chemoembolization to Treat Primary or Metastatic Liver Malignancies
- 8.01.43 - Radioembolization for Primary and Metastatic Tumors of the Liver

Microwave Tumor Ablation

Description

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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.

OBJECTIVE

The objective of this evidence review is to determine whether the use of microwave ablation improves the net health outcome in individuals with unresectable primary or metastatic solid tumors.

POLICY STATEMENT

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 3 nodules ≤ 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 or metastatic tumors other than liver or lung is considered **investigational**.

POLICY GUIDELINES

None

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

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

FDA: U.S. Food and Drug Administration.

RATIONALE

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

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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 [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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

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.¹⁰⁹ 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).¹¹⁰ 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.1.2023) list 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 (eg, resection and transplantation) and do not have large-volume extrahepatic disease.¹¹¹ 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.3.2023) 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.¹¹² Image-guided thermal ablation therapy is considered an option for the management of NSCLC lesions <3 cm. Ablation for NSCLC lesions >3 cm has been associated with higher rates of local recurrence and complications.

Guidelines on small-cell lung cancer (v.3.2023) state, "stereotactic ablative radiotherapy is an option for certain patients with medically inoperable stage I to IIA small-cell lung cancer."¹¹³

The Network guidelines on neuroendocrine tumors (v.1.2023) 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."¹¹⁴

The guidelines on kidney cancer (v.1.2024) state that thermal ablation techniques (MWA, RFA and cryotherapy) may be an option for T1 renal lesions, particularly for masses <3 cm.¹¹⁵

The guidelines on breast cancer (v.4.2023) do not address thermal ablation techniques such as MWA.¹¹⁶

Thyroid cancer guidelines from NCCN (v.4.2023) recommend ablation techniques such as cryoablation or RFA as an option for metastatic disease in select patients.¹¹⁷ 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.¹¹⁸ 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 the 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 (2007) also published guidance on MWA for HCC.¹¹⁹ This guidance indicated: "Current evidence on the safety and efficacy of MWA of hepatocellular carcinoma appears adequate to support the use of this procedure...." 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.¹²⁰ 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.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
September 2012	New Policy	Investigational for all tumor types
March 2013	Replace policy	Policy updated with literature review; reference numbers 2, 12-13, 21-25, 32 & 36 added. Policy statement unchanged.
March 2014	Replace policy	Update Policy with literature review; references 10, 11, 20 & 34 were added. Policy statement is unchanged
March 2015	Replace policy	Policy updated with literature review through September 15, 2014, reference numbers 17-18, 29, and 31 added. Reference 46 updated. Policy statement unchanged.
June 2016	Replace policy	Policy updated with literature review through February 15, 2016; references 3, 8-9, and 25-26 added. Clinical input added. Policy statement unchanged
March 2018	Archive policy	Policy updated with literature review through July 20, 2017; no references added references 44 and 47 updated. Policy statement unchanged.
December 2020	Reactivate policy	Policy updated with literature review through September 28, 2020; references added. Policy statements changed to medically necessary for lung and liver tumors; statements for other tumor types unchanged.
December 2021	Replace policy	Policy updated with literature review through August 19, 2021; references added. Policy statements unchanged.
December 2022	Replace policy	Policy updated with literature review through August 30, 2022; references added. Policy statements unchanged.
December 2023	Replace policy	Policy updated with literature review through August 25, 2023; references added. Policy statements unchanged.