MEDICAL POLICY

POLICY TITLE	MICROWAVE TUMOR ABLATION
POLICY NUMBER	MP 2.090

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☐ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☒ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**3/1/2024**

I. 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 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.** There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with these procedures.

Microwave ablation of primary or metastatic tumors other than liver or lung is considered **investigational.** There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with these procedures.

The National Comprehensive Cancer Network (NCCN) is a nonprofit alliance of cancer centers throughout the United States. NCCN develops the Clinical Practice Guidelines in Oncology which are recommendations aimed to help health care professionals diagnose, treat and manage patients with cancer. Guidelines evolve continuously as new treatments and diagnostics emerge

Cross-reference:

MP 1.121 Cryosurgical Ablation of Primary or Metastatic Liver Tumors

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital BlueCross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at:
https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

III. DESCRIPTION/BACKGROUND

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Microwave ablation (MWA) is a technique to destroy tumors and soft tissue by using microwave energy to create thermal coagulation and localized tissue necrosis. Microwave ablation is used to treat tumors not amenable to resection or 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 (e.g., ultrasound, computed tomography or magnetic resonance imaging) with sedation, or local or general anesthesia. This technique may also be referred to as microwave coagulation therapy.

MICROWAVE ABLATION

Microwave ablation (MWA) uses microwave energy to induce an ultra-high speed, 915 MHz or 2450 MHz (2.45GHz), 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 to 3 cm elliptical area 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 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 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. Microwave ablation 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 (e.g., 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.

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 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.
MedWaves Microwave Coagulation/Ablation System	General surgery use in open procedures for the coagulation and ablation of soft tissues	MedWaves Incorporated	12/1/2007	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	8/1/2010	K100786

Device	Indication	Manufacturer	Date Cleared	510(k) No.
EmprintTM Ablation System	Percutaneous, laparoscopic, and intraoperative coagulation (ablation) of soft tissue, including partial or complete ablation of non-resectable liver tumors.	Medtronic	4/2014	K133821
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
Emprint™ Ablation Platform with Thermosphere™ Technology and Emprint™ SX Ablation Platform with Thermosphere™ Technology	Antenna modification and update to instructions for use		2/2020	K193232

Device	Indication	Manufacturer	Date Cleared	510(k) No.
Certus 140 2.45 GHz Ablation System and Accessories	Ablation (coagulation) of soft tissue.	Johnson & Johnson	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
CertuSurg^{GT} 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)	Johnson & Johnson	3/1/2017	K163118

Device	Indication	Manufacturer	Date Cleared	510(k) No.
Solero Microwave Tissue Ablation (MTA) System and Accessories	Ablation of soft tissue during open procedures	Angiodynamics, Inc.	5/1/2017	K162449
Microwave Ablation System	Coagulation (ablation) of soft tissue	Surgnova Healthcare Technologies (Zhejiang) Co., Ltd	7/1/2019	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

IV. RATIONALE

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SUMMARY OF EVIDENCE

For individuals who have an unresectable primary or metastatic hepatic tumor who receive 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, 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, 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 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. 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 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 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 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=.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 overall survival, disease-specific survival, symptoms, quality of life, and treatment-related mortality and morbidity. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

V. DEFINITIONS

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N/A

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital BlueCross' Provider Services or Member Services. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

Procedure Codes							
32998	32999	47382	47399				

IX. REFERENCES

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X. POLICY HISTORY

TOP

MP 2.090	**CAC 6/24/12** New policy adopting BCBSA. Previously silent on this therapy. Now investigational.
	7/19/13 Admin code review complete
	CAC 9/24/13 Consensus review. References updated. No changes to the policy statement. Rationale added.
	CAC 9/30/14 Consensus review. References and rationale updated. No changes to the policy statements. Coding reviewed.
	CAC 9/29/15 Consensus. No change to policy statements. References and

	rationale updated. Coding reviewed
	CAC 11/29/16 Consensus. No change to policy statements. References and rationale updated. Variation reformatting**.** Coding reviewed.
	1/1/18 Administrative update. Removed end dated code 0301T and added NOC code 19499; effective 1/1/18. Medicare variations removed from Commercial Policies. Updated cross-references.
	12/29/17 Consensus review. Policy statement unchanged. Cross-References, Description/Background, Rationale and Reference sections updated.
	11/27/18 Consensus. No change to policy statements. References updated. Rationale condensed
	10/3/19 Minor Review. Policy statements changed to medically necessary for certain types of lung and liver tumors; all other tumor types will remain investigational. Background, rationale, and references and coding updated. Effective 3/1/2020
	9/4/20 Consensus Review. Policy statement unchanged. References updated.
	10/25/21 Minor Review. For the first policy statement, in the second bullet, changed "A single tumor of ≤5 cm or up to 3 nodules <3 cm each" to "A single tumor of ≤5 cm or up to 3 nodules ≤3 cm each". Removed “or lung” from the first policy statement (first statement is now for primary or metastatic hepatic tumors, the second is for primary or metastatic lung tumors). Added NCCN statement. Updated references.
	11/22/2022 Consensus Review. No change to policy statement. Product variation and FEP language revised. Background, Rationale and References updated.
	11/20/2023 Consensus review. No change to policy statement. Rationale and References updated.

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