MEDICAL POLICY – 7.01.133
Microwave Tumor Ablation

Introduction

Ablation refers to destroying tumors without removing them. Microwave ablation is a method of treating tumors using microwave energy. A small probe is placed into the tumor. The probe sends out microwave energy. The microwaves cause enough heat to kill tumor cells. Medical studies show that while this technique can destroy tumors at a particular location, cancer recurrence at other sites is common, depending on the stage and type of cancer. This policy describes when microwave ablation of tumors may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
Note: Radiofrequency ablation of primary or metastatic liver tumors is considered standard treatment and does not require medical necessity review

<table>
<thead>
<tr>
<th>Service</th>
<th>Medically Necessary</th>
</tr>
</thead>
</table>
| Microwave ablation (MWA), primary or metastatic hepatic tumors | Microwave ablation (MWA) 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)  
    OR  
  • The individual has a comorbid condition(s) that is contraindicative to surgery  
    AND  
  • A single tumor of ≤5 cm in size  
    OR  
  • 3 or fewer nodules ≤3 cm each in size                                                                                                                                                                   |

<table>
<thead>
<tr>
<th>Service</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>MWA</td>
<td>MWA of more than one single primary or metastatic tumor in the lung is considered investigational.</td>
</tr>
<tr>
<td></td>
<td>MWA of primary or metastatic tumors other than liver or lung is considered investigational.</td>
</tr>
</tbody>
</table>

**Documentation Requirements**

The individual’s medical records submitted for review should document that medical necessity criteria are met. The record should include the following:
Documentation Requirements

- Office visit notes that contain the relevant history and physical demonstrating tumor type, indicating that the tumor is unresectable with the rationale why the tumor is unresectable, and the size of the tumor(s).

Coding

According to an American Medical Association publication (Clinical Examples in Radiology, 2012, 8, [3;]), “microwave is part of the radiofrequency spectrum, and simply uses a different part of the radiofrequency spectrum to develop heat energy to destroy abnormal tissue.” Therefore, the American Medical Association recommends that microwave ablation be reported using CPT codes for radiofrequency ablation as noted in the coding table below.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td></td>
</tr>
<tr>
<td>32998</td>
<td>Ablation therapy for reduction or eradication of 1 or more pulmonary tumor(s) including pleura or chest wall when involved by tumor extension, percutaneous, radiofrequency, unilateral</td>
</tr>
<tr>
<td>47382</td>
<td>Ablation, 1 or more liver tumor(s), percutaneous, radiofrequency</td>
</tr>
<tr>
<td>50592</td>
<td>Ablation, 1 or more renal tumor(s), percutaneous, unilateral, radiofrequency</td>
</tr>
<tr>
<td>60699</td>
<td>Unlisted procedure, endocrine system (for adrenal or thyroid tumors)</td>
</tr>
<tr>
<td>HCPCS</td>
<td></td>
</tr>
<tr>
<td>C9751</td>
<td>Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3D rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (e.g., aspiration[s]/biopsy[ies]) and all mediastinal and/or hilar lymph node stations or structures and therapeutic intervention(s)</td>
</tr>
</tbody>
</table>

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).
This policy does not address microwave ablation (MWA) for the treatment of splenomegaly, ulcers, for cardiac applications, or as a surgical coagulation tool.

Evidence Review

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 amendable to resection and to treat individuals 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.

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 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 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 local recurrence, it occurs at the margins. Treatment may be repeated as needed. MWA may be used for the following purposes:

1. Control local tumor growth and prevent recurrence
2. Palliate symptoms

3. 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 individuals 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 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 individual and/or fetus have not been established, and in individuals 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 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 an individual’s candidacy while awaiting a liver transplant.

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 RFA and to surgical resection. The 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 individuals 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 five years of follow-up in individuals with a single tumor ≤5 cm or up to three nodules ≤3 cm each. In meta-analyses of observational studies, individuals receiving MWA had higher local recurrence rates and lower survival than those who received resection, but the individual 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 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 one RCT, retrospective observational studies, and systematic reviews of these studies. The 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 individuals for whom resection is not an option. In the RCT, direct comparison of MWA and RFA in individuals 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 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 individuals 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 one 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. The 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=0.54). This positive outcome should be replicated in additional RCTs. There are also no controlled studies comparing MWA to other ablation techniques in individuals with renal tumors. The evidence is insufficient to determine that the technology results in an improvement in the 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. The relevant outcomes are OS, 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.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 1.
Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT04197960</td>
<td>A Prospective Multicenter Study to Compare the Therapeutic Outcomes of Microwave Ablation with Surgical Resection for Micropapillary Thyroid Carcinoma</td>
<td>973</td>
<td>Dec 2022</td>
</tr>
<tr>
<td>NCT04626986</td>
<td>Comparison of Ultrasound Guided Percutaneous Microwave Ablation With Breast Conserving Surgery for Breast Tumor</td>
<td>300</td>
<td>May 2023</td>
</tr>
<tr>
<td>NCT04081168</td>
<td>COLLISION XL: Unresectable Colorectal Liver Metastases (3-5cm): Stereotactic Body Radiotherapy vs. Microwave Ablation (COLLISSION-XL)</td>
<td>68</td>
<td>Jan 2025</td>
</tr>
<tr>
<td>NCT03775980a</td>
<td>CIRSE Emprint Microwave Ablation Registry (CIEMAR)</td>
<td>1000</td>
<td>Jul 2026</td>
</tr>
<tr>
<td>NCT04365751</td>
<td>To Compare the Efficacy of Microwave Ablation and Laparoscopic Hepatectomy for Hepatocellular Carcinoma</td>
<td>1134</td>
<td>Dec 2026</td>
</tr>
<tr>
<td>NCT04107766a</td>
<td>NeuWave Observational Liver Ablation Registry (NOLA)</td>
<td>1500</td>
<td>Dec 2027</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.
a Denotes industry-sponsored or cosponsored trial.

Clinical Input from Physician Specialty Societies and Academic Medical Centers

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2016 Input

In response to requests, input was received from two physician specialty societies and one academic medical center while this policy was under review in 2016. This number of responses was less than optimal. Input overall was mixed. There was some support for the medical
necessity of MWA in each category, with some reviewers indicating that it was standard of care for certain tumors. However, there were no indications for which all three reviewers agreed that MWA should be medically necessary.

2011 Input

In response to requests, input was received from two physician specialty societies (three reviews) and four academic medical centers (six reviews) while this policy was in development. Eight reviewers considered MWA investigational to treat primary tumors such as hepatocellular carcinoma, benign and malignant renal tumors, lung tumors, adrenal tumors, or cholangiocarcinoma. The reviewers noted insufficient evidence and a need for further studies on MWA. However, one reviewer indicated MWA for primary tumors, including, but not limited to, hepatocellular carcinoma, benign and malignant renal tumors, lung tumors, adrenal tumors and cholangiocarcinoma, may be considered a treatment option, and another reviewer indicated that MWA for renal tumors may be considered a treatment option.

Four reviewers considered MWA investigational to treat liver metastases, and two reviewers indicated MWA for liver metastases may be considered a treatment option. One reviewer noted MWA may be appropriate for tumors not amenable to RFA or other local treatments. This reviewer also suggested MWA may be more appropriate for tumors located near large blood vessels.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a U.S. professional society, an international society with U.S. 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 non-small-cell lung cancer (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 RFA.
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 individuals who elect thermal ablation (Conditional Recommendation; Evidence Level: Grade C).\textsuperscript{110} Thermal ablation can be considered as an alternate approach in the management of T1a solid renal masses <3 cm. In these individuals, 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 RFA, cryoablation, and percutaneous alcohol injection) as a treatment option for HCC tumors in individuals who are not candidates for potential curative treatments (e.g., resection and transplantation) and do not have large-volume extrahepatic disease.\textsuperscript{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 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 individuals not receiving stereotactic ablative radiotherapy or definitive radiotherapy.\textsuperscript{112} 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.3.2023) state, "stereotactic ablative radiotherapy is an option for certain patients with medically inoperable stage I to IIA small-cell lung cancer.”\textsuperscript{113}

The Network guidelines on neuroendocrine tumors, (v. 1.2023) state that cytoreductive surgery or ablative therapies (i.e. radiofrequency, cryotherapy, microwave) may be considered in individuals 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 four lesions each smaller than 3 cm.”\textsuperscript{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.\textsuperscript{115}

The guidelines on breast cancer (v.4.2023) do not address thermal ablation techniques such as MWA.\textsuperscript{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.\textsuperscript{117} There is no specific mention of MWA.

**National Institute for Health and Care Excellence**

The NICE (2016) updated its guidance on MWA for treatment of metastases in the liver.\textsuperscript{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 individuals 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.\textsuperscript{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.\textsuperscript{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.
Medicare National Coverage

There is no national coverage determination.

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

Table 2. Selected MWA Devices Cleared by FDA

<table>
<thead>
<tr>
<th>Device</th>
<th>Indication</th>
<th>Manufacturer</th>
<th>Date Cleared</th>
<th>510(k) No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>MedWaves Microwave Coagulation/Ablation System</td>
<td>General surgery use in open procedures for the coagulation and ablation of soft tissues</td>
<td>MedWaves Incorporated</td>
<td>12/2007</td>
<td>K070356</td>
</tr>
<tr>
<td>Acculis Accu2i pMTA Microwave Tissue Ablation Applicator</td>
<td>Intraoperative coagulation of soft tissue Software addition</td>
<td>Microsoulis Holdings, Ltd</td>
<td>8/2010 11/2012</td>
<td>K094021 K122762</td>
</tr>
<tr>
<td>Acculis Accu2i pMTA Applicator and SulisV pMTA Generator</td>
<td>Coagulation (ablation) of soft tissue. May be used in open surgical as well as</td>
<td>BSD Medical Corporation</td>
<td>8/2010</td>
<td>K100786</td>
</tr>
<tr>
<td>Device</td>
<td>Indication</td>
<td>Manufacturer</td>
<td>Date Cleared</td>
<td>510(k) No.</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>Emprint Ablation System</td>
<td>percutaneous ablation procedures.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emprint Ablation System</td>
<td>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</td>
<td>Medtronic</td>
<td>4/2014</td>
<td>K133821</td>
</tr>
<tr>
<td>Emprint SX Ablation Platform with Thermosphere Technology</td>
<td></td>
<td></td>
<td>12/2016</td>
<td>K163105</td>
</tr>
<tr>
<td>Emprint Ablation Platform with Thermosphere Technology and Emprint SX Ablation Platform with Thermosphere Technology</td>
<td></td>
<td></td>
<td>9/2017</td>
<td>K171358</td>
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<td></td>
<td></td>
<td></td>
<td>2/2020</td>
<td>K193232</td>
</tr>
<tr>
<td>Certus 140 2.45 GHz Ablation System and Accessories</td>
<td>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.</td>
<td>Johnson &amp; Johnson</td>
<td>10/2010</td>
<td>K100744</td>
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<tr>
<td>Certus 140 2.45 GHz Ablation System and Accessories</td>
<td></td>
<td></td>
<td>01/2012</td>
<td>K113237</td>
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<tr>
<td>CertuSurg Surgical Tool</td>
<td></td>
<td></td>
<td>7/2013</td>
<td>K130399</td>
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<tr>
<td>Certus 140 2.45 GHz Ablation System and Accessories</td>
<td></td>
<td></td>
<td>5/2016</td>
<td>K160936</td>
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<tr>
<td>Certus 140 2.45GHz Ablation System</td>
<td></td>
<td></td>
<td>10/2018</td>
<td>K173756</td>
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<td>Device</td>
<td>Indication</td>
<td>Manufacturer</td>
<td>Date Cleared</td>
<td>510(k) No.</td>
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<tr>
<td>NEUWAVE Flex Microwave Ablation System (FLEX)</td>
<td>Ablation (coagulation) of soft tissue. Design evolution of Certus 140 2.45GHz Ablation System (K160936)</td>
<td>Johnson &amp; Johnson</td>
<td>3/2017</td>
<td>K163118</td>
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<tr>
<td>Solero Microwave Tissue Ablation (MTA) System and Accessories</td>
<td>Ablation of soft tissue during open procedures</td>
<td>Angiodynamics, Inc.</td>
<td>5/2017</td>
<td>K162449</td>
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<tr>
<td>Microwave Ablation System</td>
<td>Coagulation (ablation) of soft tissue</td>
<td>Surgnova Healthcare Technologies (Zhejiang) Co., Ltd</td>
<td>7/2019</td>
<td>K183153</td>
</tr>
<tr>
<td>NEUWAVE Microwave Ablation System and Accessories</td>
<td>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.</td>
<td>Johnson &amp; Johnson</td>
<td>11/2020</td>
<td>K200081</td>
</tr>
</tbody>
</table>

FDA: Food and Drug Administration.

References


### History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>02/27/12</td>
<td>New Policy – Add to Surgery section. Policy created with literature review through October 2011; investigational for all tumors.</td>
</tr>
<tr>
<td>07/31/12</td>
<td>Code 47379 added to the policy as this procedure can be performed laparoscopically</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>09/07/12</td>
<td>Update coding section – ICD-10 codes are now effective 10/01/14.</td>
</tr>
<tr>
<td>12/20/12</td>
<td>Update Related Policies; policy number 7.01.540 was replaced with 7.01.95.</td>
</tr>
<tr>
<td>04/16/13</td>
<td>Replace policy. Policy updated with literature review; reference numbers 2, 12-13, 21-25, 32 and 36 added. Policy statement unchanged.</td>
</tr>
<tr>
<td>03/11/14</td>
<td>Coding Update. Code 55.33 was removed per ICD-10 mapping project; this code is not utilized for adjudication of policy.</td>
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<tr>
<td>12/08/15</td>
<td>Annual Review. Policy updated with literature search; no change to the policy statement.</td>
</tr>
<tr>
<td>06/01/16</td>
<td>Annual Review, approved May 10, 2016. Policy updated with literature review through February 15, 2016; references added. Clinical input added. Policy statement unchanged. CPT code 0301T added to this policy.</td>
</tr>
<tr>
<td>01/01/19</td>
<td>Coding update, removed 0301T as it was terminated 1/1/18.</td>
</tr>
<tr>
<td>12/01/19</td>
<td>Annual Review, approved November 12, 2019. Policy updated with literature review through July 2019; references added. Policy statements changed to medically necessary for lung and liver tumors; statements for other tumor types unchanged.</td>
</tr>
<tr>
<td>06/30/2020</td>
<td>Coding update. Removed CPT codes 19499, 32999, 47399, 49999, 50592, 53899 and 76940.</td>
</tr>
<tr>
<td>08/01/20</td>
<td>Update Related Policies. 8.01.521 is now 8.01.43.</td>
</tr>
<tr>
<td>11/01/20</td>
<td>Coding update. Added HCPCS code C9751.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
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<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>01/01/23</td>
<td>Annual Review, approved December 12, 2022. Policy updated with literature review through August 30, 2022; references added. Policy statements unchanged. Changed the wording from &quot;patient&quot; to &quot;individual&quot; throughout the policy for standardization.</td>
</tr>
<tr>
<td>06/15/23</td>
<td>Update to Related Policies. 8.01.43 is replaced with 8.01.521 Radioembolization for Primary and Metastatic Tumors of the Liver.</td>
</tr>
</tbody>
</table>

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2024 Premera All Rights Reserved.

**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.
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Alaska residents: Contact the Alaska Division of Insurance via email at insurance@alaska.gov, or by phone at 907-269-7900 or 1-800-INSURAK (in-state, outside Anchorage).

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Notification: If you need help filing a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Ave SW, Room 509F, HHH Building, Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.


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