MEDICAL POLICY – 7.01.133

Microwave Tumor Ablation

**BCBSA Ref. Policy:** 7.01.133

<table>
<thead>
<tr>
<th>Effective Date:</th>
<th>7.01.133</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dec. 1, 2019</td>
<td>7.01.92</td>
</tr>
<tr>
<td>Last Revised:</td>
<td>Nov. 12, 2019</td>
</tr>
<tr>
<td>Replaces:</td>
<td>N/A</td>
</tr>
</tbody>
</table>

**RELATED MEDICAL POLICIES:**

- 7.01.92 Cryosurgical Ablation of Miscellaneous Solid Tumors Other Than Liver, Prostate, or Dermatologic Tumors
- 7.01.95 Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors
- 8.01.505 Transcatheter Arterial Chemoembolization as a Treatment for Primary or Metastatic Liver Malignancies
- 8.01.521 Radioembolization for Primary and Metastatic Tumors of the Liver

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**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.
### Service | Medically Necessary
---|---
**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

**MWA, primary or metastatic lung tumors** | MWA of primary or metastatic lung 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 ≤3 cm in size

### Service | Investigational
---|---
**MWA** | MWA of more than one single primary or metastatic tumor in the lung is considered investigational.

MWA of primary or metastatic tumors other than liver or lung is considered investigational.

### Documentation Requirements
The patient’s medical records submitted for review should document that medical necessity criteria are met. The record should include the following:
- 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).
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>19499</td>
<td>Unlisted procedure, breast</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>32999</td>
<td>Unlisted procedure, lungs and pleura</td>
</tr>
<tr>
<td>47382</td>
<td>Ablation, 1 or more liver tumor(s), percutaneous, radiofrequency</td>
</tr>
<tr>
<td>47399</td>
<td>Unlisted procedure, liver</td>
</tr>
<tr>
<td>49999</td>
<td>Unlisted procedure, abdomen, peritoneum and omentum</td>
</tr>
<tr>
<td>50592</td>
<td>Ablation, 1 or more renal tumor(s), percutaneous, unilateral, radiofrequency</td>
</tr>
<tr>
<td>53899</td>
<td>Unlisted procedure, urinary system (for renal tumors)</td>
</tr>
<tr>
<td>60699</td>
<td>Unlisted procedure, endocrine system (for adrenal or thyroid tumors)</td>
</tr>
<tr>
<td>76940</td>
<td>Ultrasound guidance for, and monitoring of, parenchymal tissue ablation</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).

Related Information

This policy does not address microwave ablation (MWA) for the treatment of splenomegaly, ulcers, for cardiac applications, or as a surgical coagulation tool.
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 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 (eg, 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

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 x 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 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 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 (eg, intestinal damage during MWA of the kidney or liver), structural damage along the probe track (eg, 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 (eg, 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 (eg, 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 liver transplantation. 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.

**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 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 patients for whom resection is not an option. Although studies had methodological limitations, they consistently showed that MWA and RFA had similar survival outcomes with up to five years of follow-up in patients with a single tumor <5 cm or up to three 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. 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 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 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. 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 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.

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>NCT02896166</td>
<td>Microwave Ablation in the Treatment of stage Non-Small Cell Lung Cancer</td>
<td>150</td>
<td>Sep 2019</td>
</tr>
<tr>
<td>NCT03045952</td>
<td>Percutaneous Microwave Ablation Under Ultrasound</td>
<td>2000</td>
<td>Dec 2019</td>
</tr>
<tr>
<td>NCT No.</td>
<td>Trial Name</td>
<td>Planned Enrollment</td>
<td>Completion Date</td>
</tr>
<tr>
<td>-----------------</td>
<td>----------------------------------------------------------------------------</td>
<td>--------------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>NCT03981497</td>
<td>Microwave Ablation for Treatment of Small Renal Tumors and Primary and Secondary Liver Neoplasms</td>
<td>250</td>
<td>Feb 2024</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

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 microwave ablation (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 radiofrequency ablation or other local treatments. This reviewer also indicated MWA may be more appropriate for tumors located near large blood vessels.

Practice Guidelines and Position Statements

National Comprehensive Cancer Network

The National Comprehensive Cancer Network guidelines on hepatobiliary cancers (v.3.2019) list microwave ablation (along with radiofrequency ablation, cryoablation, and percutaneous alcohol injection) as a treatment option for hepatocellular carcinoma (HCC) tumors in patients who are not candidates for potential curative treatments (eg, 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....” HCC tumors between 3 and 5 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 one randomized controlled trial (RCT) of MWA compared to radiofrequency ablation 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 stereotactic ablative radiotherapy (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."

**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. 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 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. 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....” 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**


**Medicare National Coverage**

There is no national coverage determination.
Regulatory Status

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 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.

Table 2. Selected Microwave Ablation 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>VivaWave™ Microwave Ablation System</td>
<td>Coagulation of soft tissue</td>
<td>Vivant Medical, Inc. ValleyLab</td>
<td>6/2002</td>
<td>K011676</td>
</tr>
<tr>
<td>Microsoulis Tissue Ablation System</td>
<td>Intraoperative coagulation of soft tissue</td>
<td>Microsoulis Americas, Inc</td>
<td>1/2006</td>
<td>K052919</td>
</tr>
<tr>
<td>MicroSurgeon Microwave Soft Tissue Ablation MTAD-100</td>
<td>Surgical ablation of soft tissue Probe/design modifications</td>
<td>MicroSurgeon, Inc.</td>
<td>8/2007</td>
<td>K070023</td>
</tr>
<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</td>
<td>K094021</td>
</tr>
<tr>
<td>Acculis Accu2i pMTA Applicator and SulisV pMTA Generator</td>
<td></td>
<td>BSD Medical Corporation</td>
<td>8/2010</td>
<td>K100786</td>
</tr>
<tr>
<td>MicroThermX Microwave Ablation System</td>
<td>Coagulation (ablation) of soft tissue. May be used in open surgical as well as percutaneous ablation procedures.</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>
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<tr>
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<tr>
<td>EmprintTM 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.</td>
<td>Covidien LLC</td>
<td>4/2014, 12/2016, 9/2017</td>
<td>K133821, K163105, K171358</td>
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<tr>
<td>EmprintTM Ablation System</td>
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<tr>
<td>Emprint™ SX Ablation Platform with Thermosphere™ Technology</td>
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<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>NeuWave Medical, Inc.</td>
<td>10/2010, 01/2012, 7/2013, 5/2016, 10/2018</td>
<td>K100744, K113237, K130399, K160936, K173756</td>
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<tr>
<td>Certus 140™ 2.45 GHz Ablation System and Accessories</td>
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<td>Certusurg™ GT Surgical Tool</td>
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<tr>
<td>Certus 140™ 2.45 GHz Ablation System and Accessories</td>
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<tr>
<td>Certus 140 2.45GHz Ablation System</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>NeuWave Medical, Inc.</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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</table>
## Device

<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>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>
</tbody>
</table>

**References**


<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>09/07/12</td>
<td>Update coding section – ICD-10 codes are now effective 10/01/14.</td>
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<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>
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<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>
</tr>
<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>
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<tr>
<td>01/01/19</td>
<td>Coding update, removed 0301T as it was terminated 1/1/18.</td>
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<tr>
<td>12/01/19</td>
<td>Annual Review, approved November 12, 2019. Policy updated with literature review</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>------</td>
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<tr>
<td></td>
<td>through July 2019; references added. Policy statements changed to medically necessary for lung and liver tumors; statements for other tumor types unchanged.</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). ©2019 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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PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592. TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file 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 Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

This Notice has Important Information. 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:

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Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

Email AppealsDepartmentInquiries@Premera.com

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost.

Call 800-722-1471 (TTY: 800-842-5357).

Arabic (Amharic):

لا يحظى هذا الإشعار معلومات هامة. قد يتوفر تحديد الملاحظات على대로 محتوى بالأعمال، في هذه الإشارات وقد تحتاج إجراء إلى تحديد محتوى للتفاصيل على الملاحظات الصحية، أو ملاحظات متعلقة بالخدمات في هذه الإشارات. لذا يوصى أن يكون الطبيب الأخصائي للنتائج. يشمل

800-722-1471 (TTY: 800-842-5357) للحصول

Chinese (Chinese):

本通知有重要的訊息。本通知可能有關於您透過 Premera Blue Cross 提交的申請或保險的重要訊息。本通知可能有關於重要日期。您可能需要在截止日期之前採取行動，以保留您的健康保險或費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話 800-722-1471 (TTY: 800-842-5357).

Italiano (Italian):

Este aviso podrá contener información importante privada cererera o acoperire, se informará a través de Premera Blue Cross. También puede haber fechas clave en este aviso. Información importante a su aplicación o cobertura por medio de Premera Blue Cross. Es posible que haya fechas clave en este aviso. Información importante a su aplicación o cobertura por medio de Premera Blue Cross. Es posible que haya fechas clave en este aviso.

Español (Spanish):
Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. Es posible que haya fechas clave en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

Tagalog (Tagalog):
Ang Paunawa na ito ay naglalaman ng mahalagang impormasyon. Ang paunawa na ito ay maaaring naglalaman ng mahalagang impormasyon tungkol sa iyong aplikasyon o pagakso sa pamamagitan ng Premera Blue Cross. Maaring maaring may mga mahalagang petsa dito sa paunawa. Maaring maaring maaring may mga mahalagang petsa dito sa paunawa. Maaring maingatang sa kanilang paksa para sa kasamaan na may impormasyon o impormasyon na may mahalagang datos para sa iyong applikasyon.

Tagalog (Tagalog):
Adunay paunawa na ito ay naglalaman ng mahalagang impormasyon. Ang paunawa na ito ay maaaring naglalaman ng mahalagang impormasyon tungkol sa iyong aplikasyon o pagakso sa pamamagitan ng Premera Blue Cross. Maaring maaring may mga mahalagang petsa dito sa paunawa. Maaring maingatang sa kanilang paksa para sa kasamaan na may impormasyon o impormasyon na may mahalagang datos para sa iyong applikasyon.

Română (Romanian):

Український (Ukrainian):
Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо страхувального покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути вказані у цьому повідомленні. Існує імовірність того, що Вам треба буде здійснити деякі коштовні строки для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дозвоніться за номером телефону 800-722-1471 (TTY: 800-842-5357).

Tiếng Việt (Vietnamese):