MEDICAL POLICY – 7.01.133
Microwave Tumor Ablation

Introduction

Ablation refers to destroying tumors without removing them. Microwave ablation is a method of trying to treat 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. More studies are needed to show which patients would benefit the most from this treatment, as well as explaining why this treatment should be used instead of other proven methods. For these reasons, microwave ablation of tumors is considered investigational (unproven).

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.
Policy Coverage Criteria

<table>
<thead>
<tr>
<th>Service</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microwave ablation (MWA)</td>
<td>Microwave ablation (MWA) of primary and metastatic tumors is considered investigational.</td>
</tr>
</tbody>
</table>

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, AMA recommends that microwave ablation should be reported using the 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>0301T</td>
<td>Destruction/reduction of malignant breast tumor with externally applied focused microwave, including interstitial placement of disposable catheter with combined temperature monitoring probe and microwave focusing sensocatheter under ultrasound thermotherapy guidance</td>
</tr>
<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>Code</td>
<td>Description</td>
</tr>
<tr>
<td>-------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>76940</td>
<td>Ultrasound guidance for, and monitoring of, parenchymal tissue ablation</td>
</tr>
</tbody>
</table>

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### Related Information

This policy does not address MWA for the treatment of splenomegaly or ulcers or as a surgical coagulation tool.

### Evidence Review

#### Description

Microwave ablation (MWA) is a technique that is used to destroy tumors and soft tissue. It generates microwave energy to create thermal coagulation and localized tissue necrosis, and has been used to treat tumors not amendable to resection. It has also been used 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

MWA is a technique that uses microwave energy to induce an ultra-high speed, 915 MHz or 2.450 MHz (2.45 GHz), alternating electric field, which causes water molecules to rotate and create 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.
(5 x 3 cm) 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. MWA may be used to:

1. Control local tumor growth and prevent recurrence

2. Palliate symptoms

3. Extend survival duration

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 are usually considered mild and may include pain and fever. Other potential 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. It should also be avoided in patients with implanted electronic devices such as 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 other tissues in order to treat many conditions. These have included 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 primary and/or palliative treatment for unresectable hepatic tumors, and also 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 liver transplantation and thus maintain a patient’s candidacy for the transplant.

Summary of Evidence

For individuals who have an unresectable primary or metastatic tumor (eg, breast, hepatic [primary or metastatic], pulmonary, renal) who receive MWA, the evidence includes case series, observational studies, cohort studies, randomized controlled trials (RCTs), and systematic reviews. Relevant outcomes are overall survival, disease-specific survival, symptoms, quality of life, and treatment-related mortality and morbidity. Available studies have shown that MWA results in a wide range of complete tissue ablation (50%-100%) depending on tumor size, with complete ablation common and nearing 100% with smaller tumors (eg, less than or equal to 3 cm). Tumor recurrence rates at ablated sites are very low. However, tumor recurrence at nonablated sites is common and may correlate with disease state (eg, in hepatocellular carcinoma). Intraoperative and postoperative minor and major complications are low, especially when tumors are smaller and accessible. Patient selection criteria and rationale for using MWA over other established techniques (eg, surgical resection, radiofrequency ablation) are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

Ongoing and Unpublished Clinical Trials

Some currently 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>NCT01340105 Microwave Versus Radiofrequency Ablation for Hepatocellular Carcinoma: a Prospective Randomized Control Trial</td>
<td>92</td>
<td>Apr 2016 (unknown)</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 provide appropriate reviewers who collaborate with and make recommendations during this process, 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 2 physician specialty societies and 1 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 3 reviewers agreed that MWA should be medically necessary.

2011

In response to requests, input was received from two physician specialty societies (3 reviews) and four academic medical centers (6 reviews) while this policy was in development. Eight reviewers considered MWA investigational to treat primary tumors such as hepatocellular carcinoma (HCC), 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 microwave ablation for primary tumors, including, but
not limited to, HCC, 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. However, 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 (RFA) or other local treatments. This reviewer also indicated microwave ablation may be more appropriate for tumors located near large blood vessels.

Practice Guidelines and Position Statements

**National Comprehensive Cancer Network (NCCN)**

The NCCN guidelines on hepatobiliary cancers (v.3.2017) lists MWA (along with RFA, 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. Ablation should only be considered when tumors are accessible by percutaneous, laparoscopic, or open approaches. The guidelines indicate HCC tumors of 3 centimeters or less may be treated with ablation alone. 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 two reviews were cited in the guideline to support recommendations for ablative techniques, but these reviews are not specific to MWA [category 2A].

NCCN guidelines for neuroendocrine tumors, (v.3.2017) do not mention MWA. Guidelines state that: "Cytoreductive surgery or ablative therapies such as radiofrequency ablation (RFA) or cryoablation 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 Clinical Excellence (NICE)**

The NICE published updated guidance on MWA for the Treatment of Metastases in the Liver in 2016, replacing a 2011 guidance. The revised guidance indicated that “Current evidence on
microwave ablation for treating liver metastases raises no major safety concerns And the evidence on efficacy is inadequate in terms of tumor ablation.”

NICE also published guidance on MWA for HCC in 2007.48 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 provided that the normal arrangements are in place for consent, audit and clinical governance.” The guidance also stated there are no major concerns about the efficacy of MWA but noted there is limited, long-term survival data are available.

**American College of Chest Physicians (CHEST)**

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.49 RFA, the most studied of the ablative modalities, has been used effectively in medically inoperable patients with small (less than 3 cm) peripheral NSCLC that are clinical stage I.

**Medicare National Coverage**

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

**Regulatory Status**

Several devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process for MWA. Covidien’s (now Medtronic’s) Evident™ Microwave Ablation System was cleared for marketing through the 510(k) process for soft tissue ablation, including partial or complete ablation of non-resectable liver tumors. The following devices have 510(k) clearance for MWA of (unspecified) soft tissue:

- BSD Medical Corporation’s (now Perseon) MicroThermX® Microwave Ablation System (MTX-180)
- Valleylab’s (subsidiary of Covidien) VivaWave® Microwave Ablation System
• Vivant’s (acquired by Valleylab in 2005) Tri-Loop™ Microwave Ablation Probe
• MicroSurgeon’s Microwave Soft Tissue Ablation Device
• Microsulis Medical’s (now part of AngioDynamics) Acculis® Accu2i
• NeuWave Medical’s Certus® 140

FDA determined that these devices were substantially equivalent to existing radiofrequency and MWA devices. FDA product code: NEY.

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>
</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>
</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>
</tr>
</tbody>
</table>

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