MEDICAL POLICY – 7.01.133
Microwave Tumor Ablation

<table>
<thead>
<tr>
<th>BCBSA Ref. Policy:</th>
<th>RELATED MEDICAL POLICIES:</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.01.133</td>
<td>7.01.95 Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors</td>
</tr>
<tr>
<td></td>
<td>7.01.526 Cryosurgical Ablation of Miscellaneous Solid Tumors Other Than Liver, Prostate, or Dermatologic Tumors</td>
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<tr>
<td></td>
<td>8.01.505 Transcatheter Arterial Chemoembolization as a Treatment for Primary or Metastatic Liver Malignancies</td>
</tr>
<tr>
<td></td>
<td>8.01.521 Radioembolization for Primary and Metastatic Tumors of the Liver</td>
</tr>
</tbody>
</table>

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POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

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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, 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>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).
This policy does not address microwave ablation (MWA) for the treatment of splenomegaly or ulcers 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 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, 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 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 are usually considered mild and 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 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, 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 instead of 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

A search of ClinicalTrials.gov in August 2018 did not identify any ongoing or unpublished trials that would likely influence this review.
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 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 Input

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, 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.2.2018) lists microwave ablation (MWA) (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 two randomized controlled trials were cited in the guidelines to support recommendations for MWA.

The Network guidelines on neuroendocrine tumors, (v.2.2018) 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 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 indicated that “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.”

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

The American College of Chest Physicians’ 2013 evidence-based guidelines on the treatment of non-small cell lung cancer noted that the role of ablative therapies in the treatment of high-risk patients with stage I non-small-cell lung cancer is evolving.46 The guidelines deal mostly with radiofrequency ablation.

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

Several devices have been cleared for marketing by the U.S. Food and Drug Administration 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 (now Valleylab in 2005) Tri-Loop™ Microwave Ablation Probe
- MicroSurgeon’s Microwave Soft Tissue Ablation Device
- Microsulis Medical’s (now AngioDynamics) Acculis® Accu2i
- NeuWave Medical’s Certus® 140

The Food and Drug Administration determined that these devices were substantially equivalent to existing radiofrequency and MWA devices. Food and Drug Administration product code: NEY.

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>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>
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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>
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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</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>-----------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
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<tr>
<td>February 15, 2016</td>
<td>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>
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</table>

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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)

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