## Title: Microwave Tumor Ablation

### Professional

**Original Effective Date:** October 1, 2016  
**Revision Date(s):** October 1, 2016; November 15, 2017; January 1, 2018; January 1, 2019; May 18, 2020  
**Current Effective Date:** May 18, 2020

### Institutional

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<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
</tr>
</thead>
</table>
| Individuals:  
- With an unresectable primary or metastatic breast tumor | Interventions of interest are:  
- Microwave ablation | Comparators of interest are:  
- Radiofrequency ablation  
- Transcatheter arterial chemoembolization  
- Cryoablation | Relevant outcomes include:  
- Overall survival  
- Disease-specific survival  
- Symptoms  
- Quality of life  
- Treatment-related morbidity |

| Individuals:  
- With an unresectable primary or metastatic hepatic tumor | Interventions of interest are:  
- Microwave ablation | Comparators of interest are:  
- Radiofrequency ablation  
- Transcatheter arterial chemoembolization  
- Cryoablation | Relevant outcomes include:  
- Overall survival  
- Disease-specific survival  
- Symptoms  
- Quality of life  
- Treatment-related morbidity  
- Treatment-related mortality |

| Individuals:  
- With an unresectable primary or metastatic lung tumor | Interventions of interest are:  
- Microwave ablation | Comparators of interest are:  
- Radiofrequency ablation  
- Transcatheter arterial chemoembolization  
- Cryoablation | Relevant outcomes include:  
- Overall survival  
- Disease-specific survival  
- Symptoms  
- Quality of life  
- Treatment-related morbidity  
- Treatment-related mortality |
**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 amenable 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.

**Objective**

The objective of this evidence review is to determine whether use of microwave ablation improves the net health outcome in individuals with unresectable primary or metastatic solid tumors.

**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 (5x3 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

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<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
</tr>
</thead>
</table>
| Individuals:  
• With an unresectable primary or metastatic renal tumor | Interventions of interest are:  
• Microwave ablation | Comparators of interest are:  
• Radiofrequency ablation  
• Transcatheter arterial chemoembolization  
• Cryoablation | Relevant outcomes include:  
• Overall survival  
• Disease-specific survival  
• Symptoms  
• Quality of life  
• Treatment-related mortality  
• Treatment-related morbidity |

| Individuals:  
• With an unresectable primary or metastatic solid tumor other than breast, liver, lung, or renal | Interventions of interest are:  
• Microwave ablation | Comparators of interest are:  
• Radiofrequency ablation  
• Transcatheter arterial chemoembolization  
• Cryoablation | Relevant outcomes include:  
• Overall survival  
• Disease-specific survival  
• Symptoms  
• Quality of life  
• Treatment-related mortality  
• Treatment-related morbidity |
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) to control local tumor growth and prevent recurrence; (2) to palliate symptoms; and (3) to prolong 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 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 a treatment for unresectable hepatic tumors, as both primary and palliative treatment, and as a bridge to liver transplant. In the latter setting, MWA is being assessed to determine whether it can reduce the
incidence of tumor progression while awaiting transplantation and thus maintain a patient’s candidacy while awaiting a liver transplant.

**Regulatory Status**

Multiple devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process for microwave ablation (MWA).

The FDA used determinations of substantial equivalence to existing radiofrequency and MWA devices to clear these devices. FDA product code: NEY.

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

**Table 1. Selected Microwave Ablation Devices Cleared by FDA**

<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 MTD-200</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 Acculis Accu2i pMTA Applicator and SulisV pMTA Generator</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>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>Emprint™ Ablation System Emprint™ Ablation System Emprint™ SX Ablation Platform with Thermosphere™ Technology</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</td>
<td>K133821</td>
</tr>
<tr>
<td>Certus 140 2.45 GHz Ablation System and Accessories 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</td>
<td>NeuWave Medical, Inc.</td>
<td>10/2010</td>
<td>K100744</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>
<tr>
<td>CertuSurg&lt;sup&gt;GT&lt;/sup&gt; Surgical Tool</td>
<td>Ablation (coagulation) of soft tissue in percutaneous, open surgical and in</td>
<td>NeuWave Medical, Inc.</td>
<td>3/2017</td>
<td>K163118</td>
</tr>
<tr>
<td>Certus 140™ 2.45 GHz Ablation System and</td>
<td>conjunction with laparoscopic surgical settings, including the partial or</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accessories</td>
<td>complete ablation of non-resectable liver tumors.</td>
<td></td>
<td></td>
<td></td>
</tr>
<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>
</tr>
<tr>
<td>Solero Microwave Tissue Ablation (MTA)</td>
<td>Ablation of soft tissue during open procedures</td>
<td>Angiodynamics, Inc.</td>
<td>5/2017</td>
<td>K162449</td>
</tr>
<tr>
<td>System and Accessories</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Microwave Ablation System</td>
<td>Coagulation (ablation) of soft tissue</td>
<td>Surgnovia Healthcare Technologies (Zhejiang) Co., Ltd</td>
<td>7/2019</td>
<td>K183153</td>
</tr>
</tbody>
</table>

FDA: Food and Drug Administration.

**POLICY**

A. Microwave ablation of primary or metastatic hepatic tumors may be considered **medically necessary** under the following conditions:
   1. The tumor is unresectable due to location of lesion[s] and/or comorbid conditions
   2. A single tumor of ≤5 cm or up to 3 nodules <3 cm each

B. Microwave ablation of primary or metastatic lung tumors may be considered **medically necessary** under the following conditions:
   1. The tumor is unresectable due to location of lesion and/or comorbid conditions
   2. A single tumor of ≤3 cm

C. Microwave ablation of more than a single primary or metastatic tumor in the lung is considered **experimental / investigational**.

D. Microwave ablation of primary or metastatic tumors other than liver or lung is considered **experimental / investigational**.

**RATIONAL**

The evidence review has been updated with searches of the MEDLINE database. The most recent literature update was performed through July 31, 2019.

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life (QOL), and ability to function including benefits and harms. Every clinical condition has
specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, two domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

**Unresectable Primary or Metastatic Breast Tumors**  
**Clinical Context and Test Purpose**  
The purpose of microwave ablation (MWA) in patients who have unresectable primary or metastatic breast tumors is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of MWA improve the net health outcome in individuals with unresectable breast tumors?

The following PICOs were used to select literature to inform this review.

**Patients**  
The relevant populations of interest are those with unresectable primary or metastatic breast tumors.

**Interventions**  
The therapy being considered is MWA.

Typically, MWA is performed under conscious sedation in an outpatient setting.

**Comparators**  
The following therapies are currently being used to make decisions about managing unresectable primary or metastatic solid tumors: radiofrequency ablation (RFA), transcatheter arterial chemoembolization (TACE), and cryoablation.

**Outcomes**  
The general outcomes of interest are overall survival (OS), tumor recurrence rates, complete ablation, and pain.

Follow-up for treatment-related morbidity is months postprocedure. Follow-up to monitor for OS and recurrence rates may be measured in years of follow-up.
Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs and systematic reviews of these studies.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews
A systematic review by Zhao and Wu (2010) assessing ablation techniques for breast cancer found that only 0% to 8% of breast cancer tumors were completely ablated with MWA. The studies identified by reviewers were mostly feasibility and pilot studies conducted in research settings.

Prospective Studies
Zhou et al (2012) reported on 41 patients treated with MWA directly followed by mastectomy for single breast tumors with a mean volume of 5.26 cm (range, 0.09-14.14 cm). Complete tumor ablation was found by microscopic evaluation in 37 (90%) of the 41 tumors ablated (95% confidence interval [CI], 76.9% to 97.3%). Reversible thermal injuries to the skin and pectoralis major muscle occurred in three patients.

Section Summary
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.

Unresectable Primary or Metastatic Hepatic Tumors

Clinical Context and Therapy Purpose
The purpose of MWA in patients who have unresectable primary or metastatic hepatic tumors is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of MWA improve the net health outcome in individuals with unresectable hepatic tumors?

The following PICOs were used to select literature to inform this review.

Patients
The relevant populations of interest are those with unresectable primary or metastatic hepatic tumors.

Interventions
The therapy being considered is MWA.

Typically, MWA is performed under conscious sedation in an outpatient setting.
Comparators
The following therapies are currently being used to make decisions about managing unresectable primary or metastatic solid tumors: RFA, TACE, and cryoablation.

Outcomes
The general outcomes of interest are OS, tumor recurrence rates, complete ablation, and pain.

Follow-up for treatment-related morbidity is months postprocedure. Follow-up to monitor for OS and recurrence rates may be measured in years of follow-up.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:
- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs and systematic reviews of these studies;
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- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews
Several systematic reviews have evaluated MWA for patients with liver tumors. The two most recent, published in 2016 and 2019, are summarized in Tables 2 and 3. One of these reviews compared MWA to resection, and the other compared MWA to RFA.

Table 2. MWA for Hepatic Tumors: Systematic Review and Meta-Analysis

<table>
<thead>
<tr>
<th>Study</th>
<th>Dates</th>
<th>Trials</th>
<th>Participants</th>
<th>Comparison</th>
<th>N (Range)</th>
<th>Design</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chinnaratha et al (2016)³</td>
<td>1980-2014</td>
<td>10</td>
<td>Adults with either very early stage, early-stage (single tumor or up to 3 nodules with each measuring ≤3 cm) or multifocal/large HCC outside Milan criteria</td>
<td>MWA vs RFA</td>
<td>1066 (42-198)</td>
<td>Observational (2 prospective, 8 retrospective)</td>
<td>5-45 months</td>
</tr>
<tr>
<td>Glassberg et al (2019)⁶</td>
<td>2006-2018</td>
<td>16</td>
<td>Adult patients with confirmed HCC or liver cancer</td>
<td>MWA vs Resection</td>
<td>965 MWA; 755 resections (22-424)</td>
<td>1 RCT, 15 observational (2 prospective, 13 retrospective)</td>
<td>15 months-5 years</td>
</tr>
</tbody>
</table>

MWA: microwave ablation; RFA: radiofrequency ablation; HCC: hepatocellular carcinoma; RCT: randomized controlled trial.
Table 3. MWA for Hepatic Tumors: Systematic Review and Meta-Analysis Results

<table>
<thead>
<tr>
<th>Study</th>
<th>Local Tumor Recurrence/Progression</th>
<th>Overall Survival</th>
<th>Disease-free Survival</th>
<th>Adverse events</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chinnaratha et al (2016)</td>
<td>MWA vs RFA</td>
<td>MWA vs RFA</td>
<td>MWA vs RFA</td>
<td></td>
</tr>
<tr>
<td>Total N</td>
<td>1298</td>
<td>538</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pooled odds ratio (95% CI)</td>
<td>I² = 23%, P = 0.23</td>
<td>1 year: 1.18 (0.46–3.03), P = 0.73</td>
<td>3 year: 0.76 (0.44–1.32), P = 0.2</td>
<td>NR</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.63 (0.29–1.38), P = 0.25</td>
<td>I² = 0%, P = 0.80</td>
<td></td>
</tr>
<tr>
<td>Glassberg et al (2019)</td>
<td>MWA vs resection</td>
<td>MWA vs resection</td>
<td>MWA vs resection</td>
<td>MWA vs resection</td>
</tr>
<tr>
<td>152/920 vs 84/710</td>
<td>2.49 (1.19, 5.22), P = 0.016</td>
<td>1 year: 0.95 (0.90, 1.01), P = 0.085</td>
<td>0.31 (0.19, 0.51)</td>
<td>Overall complications</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 years: 0.78 (0.65, 0.94), P = 0.009</td>
<td>0.24 (0.10, 0.61)</td>
<td>Major complications</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5 years: 0.83 (0.58, 1.17), P = 0.284</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

MWA: microwave ablation; RFA: radiofrequency ablation; CI: confidence interval; N: sample size; NR: not reported.

Chinnaratha et al (2016) published a systematic review of RCTs and observational studies that compared the effectiveness and safety of RFA with MWA in patients who had primary HCC. MEDLINE, EMBASE, and Cochrane Central databases were searched between 1980 and 2014 for human studies comparing the 2 technologies. The primary outcome was the risk of local tumor progression (LTP); secondary outcomes were complete ablation, OS, and major adverse events. Odds ratios were combined across studies using a random-effects model. Ten studies (one RCT, one prospective cohort, eight retrospective) were included. One study was conducted in Australia and the others in China or Japan. Using the modified Newcastle-Ottawa quality assessment scale, the reviewers rated five of ten studies high quality. The overall LTP rate was 14% (176/1298). There was no difference in LTP rates between RFA and MWA (odds ratio, 1.01; 95% CI, 0.67 to 1.50; P=0.98). The complete ablation rate, 1- and 3- year OS, and major adverse events were similar between the two modalities (P>0.05 for all). Subgroup analysis showed LTP rates were lower with MWA for treatment of larger tumors (odds ratio, 1.88; 95% CI, 1.10 to 3.23; P=0.02). No significant publication bias was detected nor was interstudy heterogeneity (I²<50%, P>0.1) observed for any measured outcomes. The reviewers concluded that MWA and RFA are equally effective and safe.

Glassberg et al (2019) conducted a systematic review of MWA compared to resection in patients with HCC or metastatic liver cancer. One RCT (Xu et al [2015]) was included; the other studies (n=15) were observational (2 prospective, 13 retrospective). Patients who received MWA had a significantly higher risk of LTP compared to those who received resection (relative risk = 3.04; P < 0.001). At one year, OS did not differ between MWA and resection but 3- and 5-year OS was
significantly higher in patients who had received resection. Overall complications and major complications were lower with MWA compared to resection. Additionally, operative time, intraoperative blood loss, and hospital length of stay were significantly lower with MWA. Some studies included patients that were nonresectable in the MWA treatment arm, but due to limited reporting and patient preference affecting which treatment was performed, the reviewers were not able to calculate the number patients who were nonresectable or to conduct subgroup analyses by resectable vs unresectable tumors. Microwave ablation was typically selected for patients with smaller and/or deeper tumors, more comorbidities, and a preference for a less invasive procedure. The reviewers concluded that MWA can be an effective and safe alternative to hepatic resection in patients or tumors that are not amenable to resection, but more studies are needed to determine the target population that would benefit most from MWA.

Randomized Controlled Trials
Three RCTs have compared MWA to RFA in patients with primary hepatic tumors (Tables 4 and 5).9,10,11

An RCT by Vietti Violi et al (2018) compared the effectiveness of RFA and MWA on treating inoperable HCC in 152 patients with up to 3 lesions of 4 cm or smaller.9 At 2 years, 6% (6/98) of lesions treated with MWA had local tumor progression vs 12% (12/104) of lesions treated with RFA (relative risk 1.62; 95% CI: 0.66 to 3.94; P=0.27). Few complications and no treatment-related deaths were reported for either group. OS at two years was not significantly different between the groups. Because some patients did not receive the allocated treatment or were lost to follow-up, the analyses were per-protocol rather than intention-to-treat. In addition, the investigators had planned to assess the effects of the treatments on larger lesions, but only a few patients had lesions of nearly 4 cm, making a detailed analysis impossible. A five-year follow-up is planned for this study.

Yu et al (2017) conducted an open-label RCT of MWA compared to RFA ablation in patients with HCC.11 Results were reported in a letter to the editor instead of a full publication. There were no significant differences between groups in rates of tumor progression, OS, or progression-free survival at one, three, or five years of follow-up. There were no differences in tumor progression rates according to tumor size or high-risk location. MWA showed higher tumor inactivation than RFA for tumors over 3 cm (6.7% vs 13.0%), but the difference was not statistically significant. Survival outcomes were not reported by tumor size. In addition to its open-label design, this study is limited because it did not report randomization and allocation concealment methods, baseline characteristics, and information on any patients lost to follow-up or with missing data.

Shibata et al (2002) reported on 72 consecutive patients with 94 small HCC nodules randomized by sealed envelope to MWA or RFA performed by a single surgeon.7 No significant differences were identified between treatment group characteristics (eg, sex, age, nodule size, Child-Pugh class, number of nodules). In the RFA group, complete ablation was seen in 46 (96%) of 48 nodules (mean size, 2.3 cm; range, 1.0-3.7 cm) and 41 (89%) of 46 nodules (mean size, 2.2 cm; range, 0.9-3.4 cm) treated with MWA (p=0.26). Treatment outcomes did not differ significantly between groups in rates of untreated disease during the 6- to 27-month follow-up (8/46 nodules for MWA vs 4/48 nodules for RFA), or major complication rates (4 vs 1, respectively). Major complications included one case of segmental hepatic infarction in the RFA group compared with one case of each of the following in the MWA group: liver abscess, cholangitis with intrahepatic bile duct dilatation, subcutaneous abscess with skin burn, and subcapsular hematoma. Life-
threatening complications were not reported. The number of treatment sessions required per nodule in the RFA group (1.1) was significantly lower than in the percutaneous MWA group (2.4; p<0.001).

The single RCT that compared MWA to resection (Xu et al [2015]8,) was included in the systematic review conducted by Glassberg et al (2019)6, and is discussed above.

**Table 4. MWA vs RFA in Patients with Hepatic Tumors: Summary of Key RCT Characteristics**

<table>
<thead>
<tr>
<th>Study; Trial</th>
<th>Countries</th>
<th>Sites</th>
<th>Dates</th>
<th>Participants</th>
<th>Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vietti Violi et al (2018)9,</td>
<td>France, Switzerland</td>
<td>4</td>
<td>2011-2015</td>
<td>Patients age 18 years or older, HCC lesion measuring 4 cm or smaller with up to 3 nodules, chronic liver disease (hepatitis) or cirrhosis with Child-Pugh score A or B, and adequate pre-ablation imaging within 4 weeks before starting the intervention.</td>
<td>76</td>
</tr>
<tr>
<td>Yu et al (2017)11, NCT 02539212</td>
<td>China</td>
<td>NR</td>
<td>2008-2015</td>
<td>Tumor size ≤5 cm, tumor number ≤3, Child-Pugh class A or B classification, no evidence of extrahepatic metastasis</td>
<td>203</td>
</tr>
<tr>
<td>Shibata et al (2002)10,</td>
<td>Japan</td>
<td>1</td>
<td>1999-2000</td>
<td>Patients with a solitary HCC nodule smaller than 4 cm or two or three nodules less than or equal to 3 cm</td>
<td>n=36</td>
</tr>
</tbody>
</table>

HCC: hepatocellular carcinoma; MWA: microwave ablation; RFA: radiofrequency ablation; RCT: randomized controlled trial.

**Table 5. Summary of Key RCT Results: MWA vs RFA in Patients with Hepatic Tumors**

<table>
<thead>
<tr>
<th>Study</th>
<th>Local Tumor Progression</th>
<th>Overall Survival</th>
<th>Disease-free Survival</th>
<th>Complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vietti Violi et al (2018)9,</td>
<td></td>
<td></td>
<td>Survival time (graph): P=0.883</td>
<td>MWA vs RFA 8/24 (33.3%) vs 16/28 (57.1%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Mortality at 6 months (MWA vs RFA): 4/24 (16.7%) vs 3/28 (10.7%); P= 0.35</td>
<td>0.05</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Mortality at 12 months (MWA vs RFA): 4/20 (20.0%) vs 5/25 (20.0%); P= 0.35</td>
<td>Major complications 7/203 (3.4%) vs 5/200 (2.5%) P=0.59</td>
</tr>
<tr>
<td>Yu et al (2017)11, NCT 02539212</td>
<td>1 year: 1.1% vs 2.1% 3 year: 4.3% vs 5.8% 5 year: 11.4% vs 19.7% P=0.11</td>
<td>Survival time (graph): P=0.91 1 year: 96.4% vs 95.9% 3 year: 81.9% vs 81.4% 5 year: 67.3% vs 72.7% 0.91</td>
<td>Disease-free survival time (graph): P=0.07 1 year: 94.0% vs 93.8% 3 year: 70.6% vs 66.0% 5 year: 36.7% vs 24.1% P=0.07</td>
<td></td>
</tr>
<tr>
<td>Study</td>
<td>Local Tumor Progression</td>
<td>Overall Survival</td>
<td>Disease-free Survival</td>
<td>Complications</td>
</tr>
<tr>
<td>-----------------------</td>
<td>-------------------------------------------------------------</td>
<td>--------------------</td>
<td>-----------------------</td>
<td>---------------</td>
</tr>
<tr>
<td>Shibata et al (2002)</td>
<td>Residual foci of untreated disease 1 year: 10% vs 4%; p=0.20</td>
<td>P=0.20</td>
<td></td>
<td>11% (4 patients)</td>
</tr>
<tr>
<td></td>
<td>2 years: 24% vs 12%; p=0.20</td>
<td></td>
<td></td>
<td>3% (1 patient)</td>
</tr>
</tbody>
</table>

RCT: randomized controlled trial; MWA: microwave ablation; RFA: radiofrequency ablation.

Tables 6 and 7 summarize the relevance, design, and conduct limitations of each trial.

### Table 6. Relevance Limitations

<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Intervention</th>
<th>Comparator</th>
<th>Outcomes</th>
<th>Follow-Up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vietti Violi et al (2018)</td>
<td></td>
<td></td>
<td>1. local tumor progression not reported</td>
<td>1. 12 months</td>
<td></td>
</tr>
<tr>
<td>Yu et al (2017)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shibata et al (2002)</td>
<td></td>
<td>Version may not be in current use</td>
<td>1. Survival not reported</td>
<td>1. 24 months</td>
<td></td>
</tr>
</tbody>
</table>

The study limitations stated in this table are those notable in the current review; this is not a comprehensive limitations assessment.

**Population key:** 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

**Intervention key:** 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.

**Comparator key:** 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

**Outcomes key:** 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.

**Follow-Up key:** 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

### Table 7. Study Design and Conduct Limitations

<table>
<thead>
<tr>
<th>Study</th>
<th>Allocation</th>
<th>Blinding</th>
<th>Selective Reporting</th>
<th>Data Completeness</th>
<th>Power</th>
<th>Statistical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yu et al (2017)</td>
<td></td>
<td>1,2 Open-label</td>
<td>2. Published as a letter to the editor</td>
<td>Not reported</td>
<td>1. not reported</td>
<td></td>
</tr>
<tr>
<td>Shibata et al (2002)</td>
<td></td>
<td>Not reported</td>
<td>Not reported</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The study limitations stated in this table are those notable in the current review; this is not a comprehensive limitations assessment.

**Allocation key:** 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.

**Blinding key:** 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.

**Selective Reporting key:** 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

**Data Completeness key:** 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).

**Power key:** 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.

**Statistical key:** 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

### Case Series

A number of case series reporting generally positive outcomes with MWA in patients with hepatic tumors have been published. Because many of these studies
are included in systematic reviews, and there is higher quality evidence from RCTs and comparative observational studies, these studies are not discussed further.

**Hepatic Metastases From Primary Cancers From Other Sites**

**Systematic Reviews**

A Health Technology Assessment by Loveman et al (2014)\(^{30}\) and a Cochrane review by Bala et al (2013)\(^{31}\) reported on ablation for liver metastasis. Reviewers found insufficient evidence to determine any benefits of MWA for liver metastasis over surgical resection.

Pathak et al (2011) conducted a systematic review of ablation techniques for colorectal liver metastases, which included 13 studies on MWA (totaln=406 patients) with a minimum of 1-year follow-up.\(^ {32}\) Mean survival rates were 73%, 30%, and 16% and ranged from 40% to 91.4%, 0% to 57%, and 14% to 32% at the 1-, 3-, and 5-year follow-ups, respectively. Minor and major complication rates were considered acceptable and ranged from 6.7% to 90.5% and 0% to 19%, respectively. Local recurrence rates ranged from 2% to 14%.

**Section Summary**

For individuals who have an unresectable primary or metastatic hepatic tumor who receive MWA, the evidence includes RCTs, comparative observational studies, case series, and systematic reviews comparing MWA to RFA and to surgical resection. 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. 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.

**Unresectable Primary or Metastatic Lung Tumors**

**Clinical Context and Therapy Purpose**

The purpose of MWA in patients who have unresectable primary or metastatic lung tumors is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of MWA improve the net health outcome in individuals with unresectable lung tumors?

The following PICOs were used to select literature to inform this review.

**Patients**

The relevant populations of interest are those with unresectable primary or metastatic lung tumors.

**Interventions**

The therapy being considered is MWA.
Typically, MWA is performed under conscious sedation in an outpatient setting.

Comparators
The following therapies are currently being used to make decisions about managing unresectable primary or metastatic solid tumor: RFA, TACE, and cryoablation.

Outcomes
The general outcomes of interest are OS, tumor recurrence rates, complete ablation, and pain. Treatment-related morbidities may vary by tumor type. For example, treatment for lung cancer may lead to pneumothorax.

Follow-up for treatment-related morbidity is months postprocedure. Follow-up to monitor for OS and recurrence rates may be measured in years of follow-up.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:
- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews
Three recent systematic reviews have compared MWA to RFA for lung cancer (Tables 8-10).\textsuperscript{33,34,35,}

Nelson et al (2019) included 12 retrospective observational studies of MWA in patients with primary or metastatic lung tumors.\textsuperscript{35} The reviewers did not pool results due to clinical and methodological heterogeneity across the studies. The studies varied with regard to patient characteristics (tumor size, histology, number of treated nodules), outcome measures, and technical experience of surgeons performing the procedures. The primary outcome was a local recurrence, and survival outcomes were not assessed. Overall, local recurrence rates ranged from 9% to 37% across the studies. Newer reports and those that targeted smaller tumors showed more favorable efficacy rates. Results in patients with multiple tumors were not reported separately. Four studies reported results by tumor size; the local recurrence rate for large tumors (> 3 or 4 cm depending on the study) were 50%, 75%, 36%, and 26%. In the same 4 studies, for small tumors (<3 or 3.5 cm depending on the study), local recurrence rates were 19%, 18%, 18%, and 5%, respectively. The most frequent adverse event with MWA was a pneumothorax requiring a chest tube. The reviewers concluded that MWA may be a useful tool in selected patients who are not ideal surgical candidates.

In a meta-analysis of observational studies, Yuan et al (2019) found higher OS for patients who received RFA compared to those who received MWA.\textsuperscript{33} However, these estimates were not directly comparable because they came from different sets of studies, and the reviewers concluded that percutaneous RFA and MWA were both effective with a high safety profile. The
studies used different patient eligibility criteria (eg, tumor size, lesion number, age, follow-up). Subgroup analyses by tumor size or tumor number were not possible from the data reported.

Jiang et al (2018) conducted a network meta-analysis to determine the effectiveness of different ablation techniques in patients with lung tumors.\(^34\) Tumor size, stage of the disease, and primary vs metastatic disease were not accounted for in the analysis. For MWA, weighted average OS rates were 82.5%, 54.6%, 35.7% 29.6%, and 16.6% at 1, 2, 3, 4, and 5 years, respectively.

Table 8. Comparison of Trials/Studies Included in SR & M-A

<table>
<thead>
<tr>
<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Vogl et al (2011)</td>
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<td>âš«</td>
<td></td>
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<tr>
<td>Lu et al (2012)</td>
<td>âš«</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Qiang et al (2012)</td>
<td>âš«</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gianpaolo et al (2013)</td>
<td>âš«</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Liu et al (2013)</td>
<td></td>
<td>âš«</td>
<td></td>
</tr>
<tr>
<td>Wei et al (2014)</td>
<td>âš«</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yang et al (2014)</td>
<td>âš«</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wei et al (2015)</td>
<td>âš«</td>
<td></td>
<td></td>
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<tr>
<td>Egashira et al (2016)</td>
<td>âš«</td>
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<td></td>
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<tr>
<td>He et al (2016)</td>
<td>âš«</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Li et al (2016)</td>
<td>âš«</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Macchi et al (2017)</td>
<td>âš«</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maxwell et al (2016)</td>
<td>âš«</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wei et al (2016)</td>
<td>âš«</td>
<td></td>
<td>âš«</td>
</tr>
<tr>
<td>Healey et al (2017)</td>
<td>âš«</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nour-Eldin et al (2017)</td>
<td>âš«</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wei et al (2017)</td>
<td>âš«</td>
<td></td>
<td>âš«</td>
</tr>
<tr>
<td>Yang et al (2017)</td>
<td>âš«</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

M-A: meta-analysis; SR: systematic reviews.

\(^{a}\)Studies of MWA only

Table 9. Characteristics of Systematic Reviews of MWA in Lung Cancer

<table>
<thead>
<tr>
<th>Study</th>
<th>Dates</th>
<th>Trials</th>
<th>Participants</th>
<th>N (Range)</th>
<th>Designs</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nelson et al (2019)(^{35}),</td>
<td>Up to October 3, 2017</td>
<td>12</td>
<td>Primary or secondary lung malignancies</td>
<td>985 (15-184)</td>
<td>12 retrospective observational; excluded case series with &lt;30 lesions</td>
<td>9-47 months</td>
</tr>
<tr>
<td>Yuan et al (2019)(^{33}),</td>
<td>2010-2017</td>
<td>12</td>
<td>Primary or secondary lung malignancies</td>
<td>800 (15-183)</td>
<td>12 retrospective, observational</td>
<td>Median 10-35 months (range 3-75 months), NR in 3 studies</td>
</tr>
<tr>
<td>Jiang et al (2018)(^{34}),</td>
<td>Up to December 31, 2017</td>
<td>9</td>
<td>Primary lung cancer or pulmonary metastases from other primary tumors</td>
<td>438 (5-183)</td>
<td>1 RCT, 8 retrospective observational; excluded studies that used other treatments combined with thermal ablation</td>
<td>Median 12-35 months (range 3-108 months)</td>
</tr>
</tbody>
</table>

MWA: microwave ablation; RCT: randomized controlled trial; N: sample size; NR: not reported.
Table 10. Results of Systematic Reviews of MWA in Lung Cancer

<table>
<thead>
<tr>
<th>Study</th>
<th>Overall Survival</th>
<th>Progression-free Survival</th>
<th>Local Recurrence Rate</th>
<th>Adverse Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Range of N</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Range of effect sizes</td>
<td>NR (primary analysis was local recurrence)</td>
<td>NR</td>
<td>Range 9%-37% 25% or greater (n=4 studies); less than 25% (n=7 studies); less than 15% (n=2 studies)</td>
<td>Pneumothorax: 1%-15%; skin burns: 1.5%-6%; periprocedural mortality: 1 patient (0.5%) from ventricular tachycardia</td>
</tr>
<tr>
<td>Yuan et al (2019)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pooled estimate (95% CI); I²</td>
<td>1 year: 79.3 (73.7-85.0); 2 years: 43.1 (1.5-84.7) 3 years: 56.0 (41.1-70.9)</td>
<td>1 year: 64.8 (37.1-92.4) 2 year: 43.1 (1.5-84.7) 3 years: 56.0 (41.1-70.9)</td>
<td>1 year: 84.6 (72.9-96.3) 2 years: 68.5 (51.8-85.1) 3 years: 72.2 (64.5-79.9) 4 years: 74.1 (67.0-81.2) 5 years: 48.0 (23.8-72.2)</td>
<td>Pneumothorax: 33.9% Pneumothorax needing intervention: (11.0%) Pleural effusion 9.6% Pleural effusion needing intervention: 0.3%</td>
</tr>
<tr>
<td>Jiang et al (2018)</td>
<td>Weighted average</td>
<td></td>
<td>Weighted average 10.9%</td>
<td>Major complications, weighted average 22.5%</td>
</tr>
<tr>
<td></td>
<td>1 year: 82.5% 2 years: 54.6% 3 years: 35.7% 4 years: 29.6% 5 years: 16.6%</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

MWA: microwave ablation; CI: confidence interval; N: sample size; NR: not reported.

RCTs
There is one RCT of MWA compared to RFA for lung tumors, conducted by Macchi et al (2017), (Tables 11 and 12).36 Patients were eligible for the study if they had a single tumor up to 5 cm, and up to five metastases up to 5 cm. However, at baseline, the mean tumor size was 2.21 cm (standard deviation 0.89) in the MWA group and 1.64 cm (standard deviation 0.80) in the RFA group. Mortality rates at 6 and 12 months did not differ between groups, and complications were significantly lower in the MWA group. Limitations of this study are summarized in Tables 13 and 14 and include its small sample size, lack of reporting on blinding, and relatively short follow-up period (12 months). Results were not reported by tumor size or the number of metastases.

Table 11. Summary of Key RCT Characteristics: MWA vs RFA in Patients with Lung Tumors

<table>
<thead>
<tr>
<th>Study; Trial</th>
<th>Countries</th>
<th>Sites</th>
<th>Dates</th>
<th>Participants</th>
<th>Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Macchi et al (2017)36</td>
<td>Italy</td>
<td>Multisite, NR</td>
<td>NR</td>
<td>MWA n=24</td>
<td>RFA n=28</td>
</tr>
<tr>
<td>Study; Trial</td>
<td>Countries</td>
<td>Sites</td>
<td>Dates</td>
<td>Participants</td>
<td>Interventions</td>
</tr>
<tr>
<td>-------------</td>
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<td>---------------</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>with pulmonary metastases, number of metastases 5 or fewer, each with maximum diameter of 5 cm</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Mean tumor size at baseline: Overall: 1.90 cm (± 0.89 cm)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>MWA: 2.21 cm ± 0.89</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>RFA: 1.64 cm ± 0.80</td>
<td></td>
</tr>
</tbody>
</table>

RCT: randomized controlled trial; MWA: microwave ablation; NR: not reported; RFA: radiofrequency ablation.

### Table 12. Summary of Key RCT Results: MWA vs RFA in Patients with Lung Tumors

<table>
<thead>
<tr>
<th>Study</th>
<th>Local Tumor Recurrence</th>
<th>Survival time</th>
<th>Mortality at 6 months</th>
<th>Mortality at 12 months</th>
<th>Complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Macchi et al (2017)</td>
<td>NR</td>
<td>(graph only)</td>
<td>4/24 (16.7%)</td>
<td>4/20 (20.0%)</td>
<td>8/24 (33.3%)</td>
</tr>
<tr>
<td>MWA</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RFA</td>
<td></td>
<td></td>
<td>3/28 (10.7%)</td>
<td>5/25 (20.0%)</td>
<td>16/28 (57.1%)</td>
</tr>
<tr>
<td>p-value</td>
<td></td>
<td>0.883</td>
<td>0.35</td>
<td></td>
<td>0.05</td>
</tr>
</tbody>
</table>

RCT: randomized controlled trial; MWA: microwave ablation; NR: not reported; RFA: radiofrequency ablation.

### Table 13. Relevance Limitations

<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Intervention</th>
<th>Comparator</th>
<th>Outcomes</th>
<th>Follow-Up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Macchi et al (2017)</td>
<td>1. Did not report results by tumor size, histology, or number of tumors 2. combined patients with primary and metastatic tumors in analyses</td>
<td>1. Local recurrence not reported</td>
<td>1. 12 months only</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The study limitations stated in this table are those notable in the current review; this is not a comprehensive limitations assessment.

### Table 14. Study Design and Conduct Limitations

<table>
<thead>
<tr>
<th>Study</th>
<th>Allocation</th>
<th>Blinding</th>
<th>Selective Reporting</th>
<th>Data Completeness</th>
<th>Power</th>
<th>Statistical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Macchi et al (2017)</td>
<td>Not reported</td>
<td></td>
<td>1. power calculation not reported</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The study limitations stated in this table are those notable in the current review; this is not a comprehensive limitations assessment.
Section Summary
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.

Unresectable Primary or Metastatic Renal Tumors
Clinical Context and Therapy Purpose
The purpose of MWA in patients who have unresectable primary or metastatic renal tumors is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of MWA improve the net health outcome in individuals with unresectable renal tumors?

The following PICOs were used to select literature to inform this review.

Patients
The relevant populations of interest are those with unresectable primary or metastatic renal tumors.

Interventions
The therapy being considered is MWA.

Typically, MWA is performed under conscious sedation in an outpatient setting.

Comparators
The following therapies are currently being used to make decisions about managing unresectable primary or metastatic solid tumors: RFA, TACE, and cryoablation.
Outcomes
The general outcomes of interest are OS, tumor recurrence rates, complete ablation, and pain. Treatment-related morbidities may vary by tumor type. For example, treatment for lung cancer may lead to pneumothorax.

Follow-up for treatment-related morbidity is months postprocedure. Follow-up to monitor for OS and recurrence rates may be measured in years of follow-up.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:
- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews
In a systematic review and meta-analysis, Katsanos et al (2014) compared thermal ablation (MWA and RFA) with surgical nephrectomy for small renal tumors (mean size, 2.5 cm). The analysis included 1 randomized study on MWA (described below) and 5 cohort studies on RFA (total n=587 patients). In the ablation group, complication rates and renal function declines were significantly higher than in the nephrectomy group (p=0.04 and p=0.03, respectively). The local recurrence rate was 3.6% in both groups (relative risk, 0.92; 95% CI, 0.4 to 2.14; p=0.79) and DFS up to 5 years did not differ significantly between groups (hazard ratio, 1.04; 95% CI, 0.48 to 2.24; p=0.92).

Martin et al (2013) conducted a meta-analysis comparing MWA with cryoablation for small renal tumors. The analysis included 7 MWA studies (n=164 patients) and 44 cryoablation studies (n=2989 patients). Selected studies were prospective or retrospective, nonrandomized, noncomparative studies. Mean follow-up duration was shorter for MWA (17.86 months) than for cryoablation (30.22 months; p=0.07). Mean tumor size was significantly larger in the MWA studies than in the cryoablation studies (2.58 cm vs 3.13 cm, respectively, p=0.04), LTP (4.07% vs 2.53%, respectively; p=0.46) and progression to metastatic disease (0.8% vs 0%, respectively; p=0.12) did not differ significantly.

Randomized Controlled Trial
Guan et al (2012) reported on a prospective randomized study that compared the use of MWA with partial nephrectomy (the criterion standard of nephron-sparing surgical resection) for solitary renal tumors less than 4 cm. Forty-eight patients received MWA and 54 had partial nephrectomy. Patients in the MWA group (6 [23.5%]) had significantly fewer postoperative complications than in the partial nephrectomy group (18 [33.3%]; p=0.019). MWA patients also had significantly less postoperative renal function declines (p<0.009) and estimated perioperative blood loss (p<0.001) than partial nephrectomy patients. At last follow-up, estimated glomerular filtration rate declines in both groups were similar (p=1.00). Disease-specific deaths did not
occur, and overall local recurrence-free survival by Kaplan-Meier estimates at 3 years was 91.3% for MWA and 96.0% for partial nephrectomy (p=0.541).

Case Series
Yu et al (2012) reported on a retrospective review of 46 patients treated with MWA for renal cell carcinoma. Complete ablation occurred in 98% (48/49) of tumors (mean tumor size, 3.0 cm). At a median follow-up of 20.1 months, all 46 patients were metastasis-free. OS rates were 100% at 1 and 2 years and 97.8% at 3 years.

Muto et al (2011) reported on complete tumor coagulation necrosis in 10 patients treated with MWA for clear cell renal carcinoma (median tumor size, 2.75 cm). No complications were reported during or after the procedure. Bai et al (2010) reported complete laparoscopic MWA in 17 of 18 clear cell renal carcinoma tumors (mean tumor size, 2.8 cm). In this study, evidence of disease progression was not found at a median follow-up of 20 months. Complications reported were mild (18.2%), and renal function did not significantly deteriorate.

In a study of 10 patients with solid-enhancing renal tumors (median size, 3.65 cm) who were treated with MWA, Castle et al (2011) reported tumor recurrence in 3 of 8 tumors at a mean follow-up of 17.9 months. Twenty percent of patients experienced intraoperative complications while 40% experienced postoperative complications, including perinephric hematoma, splenic capsular tear, pleuritic chest pain, skin burn, fever, hematuria, genitofemoral neuralgia, and urinoma.

In another study, Guan et al (2010) reported on the safety of MWA for renal hamartoma. In this case series, 15 of 16 patients had complete tumor ablation. Disease recurrence was not reported at a median follow-up of 16 months.

Section Summary
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.

Unresectable Primary or Metastatic Solid Tumors Other than Breast, Hepatic, Lung, or Renal
Clinical Context and Therapy Purpose
The purpose of MWA in patients who have unresectable primary or metastatic solid tumors other than breast, hepatic, lung, or renal is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of MWA improve the net health outcome in individuals with unresectable solid tumors other than breast, hepatic, lung, or renal?

The following PICOs were used to select literature to inform this review.
Patients
The relevant populations of interest are those with unresectable primary or metastatic solid tumors other than breast, hepatic, lung, or renal.

Interventions
The therapy being considered is MWA.

Typically, MWA is performed under conscious sedation in an outpatient setting.

Comparators
The following therapies are currently being used to make decisions about managing unresectable primary or metastatic solid tumors: RFA, TACE, and cryoablation.

Outcomes
The general outcomes of interest are OS, tumor recurrence rates, complete ablation, and pain. Treatment-related morbidities may vary by tumor type. For example, treatment for lung cancer may lead to pneumothorax.

Follow-up for treatment-related morbidity is months postprocedure. Follow-up to monitor for OS and recurrence rates may be measured in years of follow-up.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

No RCTs on the use of MWA for other tumors or conditions were identified. A systematic review of ablation therapies, including MWA, for locally advanced pancreatic cancer was published by Keane et al (2014). Reviewers found limited evidence on the use of MWA for pancreatic cancer.

Case studies and retrospective reviews on the use of MWA for adrenal carcinoma, metastatic bone tumors, intrahepatic primary cholangiocarcinoma, benign thyroid tumors, and other nononcologic conditions (ie, bleeding peptic ulcers, esophageal varices, secondary hypersplenism) were identified.

Section Summary
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.

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 RCTs, comparative observational studies, case series, and systematic reviews comparing MWA to RFA and to surgical resection. 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. 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.

**Clinical Input 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 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 suggested 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 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 cm and 5 cm 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 ablation major vessels, bile ducts, the diaphragm, or other abdominal
organs. However, only one 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 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 tumour 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

**U.S. Preventive Services Task Force Recommendations**
Not applicable.

**Ongoing and Unpublished Clinical Trials**
Some currently ongoing and unpublished trials that might influence this review are listed in Table 15.
### Table 15. Summary of Key Trials

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<td>NCT03981497 Microwave Ablation for Treatment of Small Renal Tumors and Primary and Secondary Liver Neoplasms</td>
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<td>February 2024</td>
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NCT: national clinical trial.

### CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

### CPT/HCPCS

- 32998 Ablation therapy for reduction or eradication of 1 or more pulmonary tumor(s) including pleura or chest wall when involved by tumor extension, percutaneous, including imaging guidance when performed, unilateral; radiofrequency
- 47380 Ablation, open, of 1 or more liver tumor(s); radiofrequency
- 47382 Ablation, 1 or more liver tumor(s), percutaneous, radiofrequency

- There are no CPT codes specific to microwave ablation.
- According to an American Medical Association (AMA) 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 be reported using CPT codes for radiofrequency ablation – 32998 (pulmonary), 47382 (liver), and 50592 (renal).
- If there is no specific CPT code for ablation, the unlisted CPT code for the anatomic area should be reported, such as code 60699 for unlisted procedure, endocrine system (for adrenal or thyroid ablation), 19499 for the breast.

### Diagnoses

- C22.0 Liver cell carcinoma
- C22.2 Hepatoblastoma
- C22.3 Angiosarcoma of liver
- C22.4 Other sarcomas of liver
- C22.7 Other specified carcinomas of liver
- C22.8 Malignant neoplasm of liver, primary, unspecified as to type
- C22.9 Malignant neoplasm of liver, not specified as primary or secondary
- C34.11 Malignant neoplasm of upper lobe, right bronchus or lung
- C34.12 Malignant neoplasm of upper lobe, left bronchus or lung
- C34.2 Malignant neoplasm of middle lobe, bronchus or lung
- C34.31 Malignant neoplasm of lower lobe, right bronchus or lung
C34.32 Malignant neoplasm of lower lobe, left bronchus or lung  
C34.81 Malignant neoplasm of overlapping sites of right bronchus and lung  
C34.82 Malignant neoplasm of overlapping sites of left bronchus and lung  
C34.91 Malignant neoplasm of unspecified part of right bronchus or lung  
C34.92 Malignant neoplasm of unspecified part of left bronchus or lung  
C78.01 Secondary malignant neoplasm of right lung  
C78.02 Secondary malignant neoplasm of left lung  
C78.7 Secondary malignant neoplasm of liver and intrahepatic bile duct  
C7B.02 Secondary carcinoid tumors of liver

### REVISIONS

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<td>2. A single tumor of ≤5 cm or up to 3 nodules &lt;3 cm each</td>
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<td>B. Microwave ablation of primary or metastatic lung tumors may be considered medically necessary under the following conditions:</td>
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<tr>
<td></td>
<td>1. The tumor is unresectable due to location of lesion and/or comorbid conditions</td>
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<td>2. A single tumor of ≤3 cm</td>
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<td>C. Microwave ablation of more than a single primary or metastatic tumor in the lung is considered experimental / investigational.</td>
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<td>D. Microwave ablation of primary or metastatic tumors other than liver or lung is considered experimental / investigational.</td>
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