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<b>Preauthorization</b>	No	<b>Review Dates:</b> 05/13, 05/14	

*The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is not required but recommended if, despite this Protocol position, you feel this service is medically necessary.** Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

### Description

Microwave ablation (MWA) is a technique to destroy tumors and soft tissue by using microwave energy to create thermal coagulation and localized tissue necrosis. MWA is used to treat tumors considered to be inoperable or not amenable to resection or to treat patients ineligible for surgery due to age, presence of comorbidities, or poor general health. MWA may be performed as an open procedure, laparoscopically, percutaneously or thoracoscopically under image guidance (e.g., ultrasound, computed tomography [CT] or magnetic resonance imaging [MRI]) with sedation, or local or general anesthesia. This technique may also be referred to as microwave coagulation therapy.

### Background

Microwave ablation (MWA) is a technique in which the use of microwave energy induces an ultra-high speed, 915 MHz or 2.450 MHz (2.45 GHz), alternating electric field, which causes water molecule rotation and the creation of 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, approximately 2-3 cm elliptical area (5 x 3 cm) of tissue ablation. In tumors greater than 2 cm in diameter, two to three antennas may be used simultaneously to increase the targeted area of MWA and shorten operative time. Multiple antennas may also be used simultaneously to ablate multiple tumors. Tissue ablation occurs quickly, within one minute after a pulse of energy, and multiple pulses may be delivered within a treatment session, depending on the size of the tumor. 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 edges. Treatment may be repeated as needed. MWA may be used to: 1) control local tumor growth and prevent recurrence; 2) palliate symptoms; and 3) extend survival duration.

Complications from MWA are usually considered mild and may include pain and fever. Other potential complications associated with MWA include those caused by heat damage to normal tissue adjacent to the tumor (e.g., intestinal damage during MWA of the kidney or liver), structural damage along the probe track (e.g., pneumothorax as a consequence of procedures on the lung), liver enzyme elevation, liver abscess, ascites, pleural effusion, diaphragm injury or secondary tumors if cells seed during probe removal. MWA should be avoided in pregnant patients since potential risks to the patient and/or fetus have not been established and in patients with implanted electronic devices such as implantable pacemakers that may be adversely affected by microwave power output.

MWA is an ablative technique similar to radiofrequency or cryosurgical ablation. However, MWA has some potential hypothetical advantages over radiofrequency or cryosurgical ablation. In MWA, the heating process is active, which produces higher temperatures than the passive heating of radiofrequency ablation and should allow for more complete thermal ablation in a shorter period of time. The higher temperatures reached with MWA (over 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 have electrical current flow through patients and does not require that grounding pads be used during the procedure, since there is no risk of skin burns. Additionally, MWA does not produce electric noise, which allows ultrasound guidance to occur during the procedure without interference, unlike radiofrequency ablation. Finally, MWA can be completed in less time than radiofrequency ablation, since multiple antennas can be used simultaneously.

MWA was first used percutaneously in 1986 as an adjunct to liver biopsy. Since that time, MWA has been used for ablation of tumors and tissue for the treatment of many conditions including: hepatocellular carcinoma, 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 hypothesized advantages of MWA for these cancers include improved local control and those common to any minimally invasive procedure (e.g., preserving normal organ tissue, decreasing morbidity, decreasing length of hospitalization).

Hepatic Tumors. Hepatic tumors can arise either as primary liver cancer (hepatocellular carcinoma, HCC) or by metastasis to the liver from other primary cancer sites. Local therapy for hepatic metastasis may be indicated when there is no extrahepatic disease, which rarely occurs for patients with primary cancers other than colorectal carcinoma or certain neuroendocrine malignancies. At present, surgical resection with adequate margins or liver transplantation constitutes the only treatments available with demonstrated curative potential. Partial liver resection, hepatectomy, is considered the gold standard. However, the majority of hepatic tumors are unresectable at diagnosis, due either to their anatomic location, size, number of lesions, or underlying liver reserve.

Various locoregional therapies for unresectable liver tumors have been investigated including: microwave coagulation, radiofrequency ablation, cryosurgical ablation (cryosurgery), laser ablation, trans-hepatic artery embolization/chemoembolization (TACE), percutaneous ethanol injection, and radioembolization (Yttrium-90 microspheres).

MWA has been investigated as a treatment for unresectable hepatic tumors, both as primary treatment, palliative treatment, and as a bridge to liver transplant. In the latter setting, it is hoped that MWA will reduce the incidence of tumor progression while awaiting transplantation and thus maintain a patient’s candidacy for liver transplant during the wait time for a donor organ.

Renal Cell Carcinoma. Radical nephrectomy remains the principal treatment of renal cell carcinoma; however, partial nephrectomy or nephron-sparing surgery has been shown to be as effective as radical nephrectomy, with comparable long-term recurrence-free survival rates, in a select group of patients. Prognosis drops precipitously if the tumor extends outside the kidney capsule, since chemotherapy is relatively ineffective against metastatic renal cell carcinoma. Alternative therapies such as MWA are of interest in patients with small renal tumors when preservation of renal function is necessary (e.g., in patients with marginal renal function, a solitary kidney, bilateral tumors) and in patients with comorbidities that would render them unfit for surgery. Another consideration would be in patients at high risk of developing additional renal cancers (as in von Hippel-Lindau disease).

### *Regulatory Status*

There are several devices cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process for MWA. Covidien's (a subsidiary of Tyco Healthcare) Evident™ Microwave Ablation System has 510(k) clearance for soft tissue ablation, including partial or complete ablation of nonresectable liver tumors. The following devices have 510(k) clearance for MWA of (unspecified) soft tissue:

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

These devices are considered substantially equivalent to previously FDA-approved radiofrequency and MWA devices.

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

### *Related Protocols*

Cryosurgical Ablation of Primary or Metastatic Liver Tumors

Radiofrequency Ablation of Primary or Metastatic Liver Tumors

Cryosurgical Ablation of Miscellaneous Solid Tumors Other Than Liver, Prostate, or Dermatologic Tumors

Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors

Transcatheter Arterial Chemoembolization (TACE) to Treat Primary or Metastatic Liver Malignancies

Radioembolization for Primary and Metastatic Tumors of the Liver

### **Policy (Formerly Corporate Medical Guideline)**

Microwave ablation of primary and metastatic tumors is considered **investigational**.

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Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

### **References**

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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