Protocol

Microwave Tumor Ablation

(701133)

Medical Benefit		**Effective Date**: 07/01/13	**Next Review Date**: 01/20
Preauthorization	No	**Review Dates**: 05/13, 05/14, 01/15, 01/16, 01/17, 01/18, 01/19	

This protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. 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.

Populations	Interventions	Comparators	Outcomes
Individuals: • With an unresectable primary or metastatic solid tumor (e.g., breast, hepatic [primary or metastatic], pulmonary, 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

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 (e.g., ultrasound, computed tomography, magnetic resonance imaging) with sedation, or local or general anesthesia. This technique is also referred to as microwave coagulation therapy.

SUMMARY OF EVIDENCE

For individuals who have an unresectable primary or metastatic tumor (e.g., breast, hepatic [primary or metastatic], pulmonary, renal) who receive MWA, the evidence includes case series, observational studies, cohort studies, randomized controlled trials (RCTs), and systematic reviews. Relevant outcomes are overall survival, disease specific survival, symptoms, quality of life, and treatment-related mortality and morbidity. Available studies have shown that MWA results in a wide range of complete tissue ablation (50%-100%) depending on tumor size, with complete ablation common and nearing 100% with smaller tumors (e.g., three cm or less). Tumor recurrence rates at ablated sites are very low. However, tumor recurrence at nonablated sites is common and may correlate with disease state (e.g., 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 (e.g., surgical resection, radiofrequency

ablation) are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

POLICY

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

BACKGROUND

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, two- to three-cm elliptical area (5*3 cm) of tissue ablation. In tumors greater than two cm in diameter, two to three antennas may be used simultaneously to increase the targeted area of MWA and shorten the operative time. Multiple antennas may also be used simultaneously to ablate multiple tumors. Tissue ablation occurs quickly, within one minute after a pulse of energy, and multiple pulses may be delivered within a treatment session, depending on tumor size. The cells killed by MWA are typically not removed but are gradually replaced by fibrosis and scar tissue. If there is a 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.

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 (more than 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 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 (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 women because potential risks to the patient and/or fetus have not been established, and in patients with implanted electronic devices (e.g., 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 (e.g., 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

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

- BSD Medical'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 System;
- Microsulis Medical's (now AngioDynamics) Acculis® Accu2i; and
- NeuWave Medical's Certus® 140.

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

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

RELATED PROTOCOLS

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

Cryosurgical Ablation of Primary or Metastatic Liver Tumors

Radioembolization for Primary and Metastatic Tumors of the Liver

Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors

Radiofrequency Ablation of Primary or Metastatic Liver Tumors

Transcatheter Arterial Chemoembolization to Treat Primary or Metastatic Liver Malignancies

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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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