Microwave Tumor Ablation

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.

Microwave ablation (MWA) is a technique in which the use of microwave energy induces an ultra-high speed, 915 MHz or 2450 MHz (2.45GHz), 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, 2-3 antennas may be used simultaneously to increase the targeted area of MWA and shorten operative time. Multiple antennas may also be used simultaneously to ablate multiple tumors. Tissue ablation occurs quickly, within 1 minute after a pulse of energy, and multiple pulses may be delivered within a treatment session depending on 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
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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 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).

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.

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 non-resectable 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 Acculis Accu2i; and
• NeuWave Medical’s Certus 140

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

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

Related Policies:
Cryosurgical 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
Chemoembolization of the Hepatic Artery, Transcatheter Approach
Radioembolization for Primary and Metastatic Tumors of the Liver

***Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.
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**Policy**

Microwave tumor ablation is considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.

**Benefits Application**

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

**When Microwave Tumor Ablation is covered**

Not applicable.

**When Microwave Tumor Ablation is not covered**

Microwave ablation of primary and metastatic tumors is considered investigational for all applications.

**Policy Guidelines**

In summary, based on review of the published data (which consists largely of small case series and limited randomized trials) and clinical input, there is insufficient evidence to permit conclusions concerning the comparative effectiveness of microwave ablation (MWA) to other ablative techniques on health outcomes. Therefore, MWA of hepatocellular carcinoma, liver metastases from primary cancers from other sites, renal cell carcinoma, other renal tumors and all other tumors is considered investigational.

Based on review of the published data (which consist largely of small case series and limited randomized trials) and clinical input, there is insufficient evidence to permit conclusions concerning the comparative effectiveness of microwave ablation (MWA) to other ablative techniques on health outcomes. Therefore, MWA of hepatocellular carcinoma (HCC), liver metastases from primary cancers from other sites, renal cell carcinoma, other renal tumors and all other tumors is considered investigational. Studies show MWA results in a wide range of complete tissue ablation (50%-100%) depending on tumor size with complete ablation common and nearing 100% with smaller tumors (eg, ≤3 cm). Recurrence of tumors at ablated sites is very low. However, recurrence of tumors at nonablated sites is common and may be due to the nature of the disease state (eg, in HCC). Intraoperative and postoperative minor and major complications are low, especially in cases where tumors are smaller and more accessible. While some earlier studies found MWA required more treatment sessions to achieve adequate ablation, more recent studies using newer MWA technology that deliver larger ablation zones with cooled-shaft antennas have demonstrated shorter ablation times and fewer complications.

While MWA has theoretical advantages over radiofrequency ablation (RFA), studies on the use of MWA with larger numbers of patients and longer follow-up are needed to adequately assess health outcomes. Patient selection criteria and rationale for using MWA over other established techniques such as surgical resection or RFA are needed. Results of the ongoing phase 3 trial comparing MWA to RFA will provide additional information in determining the role of MWA in the treatment of HCC. Information from additional future studies may indicate a role for MWA for the treatment of tumors for control of local tumor growth, palliation of symptoms, and extended survival durations in tumors that are not amenable to resection or in patients who are not surgical candidates. However, in total, the current available evidence is insufficient to permit conclusions on net health outcomes of MWA of tumors, and this technique is
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considered investigational.

**Billing/Coding/Physician Documentation Information**

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

*Applicable codes: There is no specific code for this service.*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

**Scientific Background and Reference Sources**

- Medical Director – 3/2012


**Policy Implementation/Update Information**

- **4/17/12** New policy. “Microwave ablation of primary and metastatic tumors is considered investigational for all applications.” Medical Director review 3/12/2012. Notification given 4/17/12. Policy effective 7/24/12. (btw)
- **1/15/13** Specialty Matched Consultant Advisory Panel review 12/4/2012. No change to policy intent. (btw)
- **4/1/13** Reference added. (btw)
- **12/10/13** Specialty Matched Consultant Advisory Panel review 11/20/2013. No change to policy. (btw)
- **12/9/14** Reference added. Specialty Matched Consultant Advisory Panel review 11/24/2014. No change to policy intent. (lpr)
- **12/30/15** Policy Guidelines and Description sections updated. Reference added. Specialty Matched Consultant Advisory Panel review 11/18/2015. No change to policy statement. (lpr)
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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.