

## Corporate Medical Policy

### Microwave Tumor Ablation

**File Name:** microwave\_tumor\_ablation  
**Origination:** 12/2011  
**Last CAP Review:** 11/2018  
**Next CAP Review:** 11/2019  
**Last Review:** 12/2018

#### Description of Procedure or Service

---

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 are 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 time. The higher temperatures reached with MWA (over 100° C) can overcome

# Microwave Tumor Ablation

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, 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 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 (now Perseon) 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

FDA determined that these devices were substantially equivalent to existing 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.**

# Microwave Tumor Ablation

## 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

---

For individuals who have an unresectable primary or metastatic tumor (eg, breast, hepatic [primary or metastatic], pulmonary, renal) who receive microwave ablation (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 (eg,  $\leq 3$  cm). Tumor recurrence rates at ablated sites are very low. However, tumor recurrence at nonablated sites is common and may correlate with disease state (eg, in hepatocellular carcinoma). Intraoperative and postoperative minor and major complications are low, especially when tumors are smaller and accessible. Patient selection criteria and rationale for using MWA over other established techniques (eg, surgical resection, radiofrequency ablation) are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

## 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.bcsnc.com](http://www.bcsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable codes: C9751*

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

---

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.133, 12/8/11

Medical Director – 3/2012

# Microwave Tumor Ablation

Specialty Matched Consultant Advisory Panel – 12/2012

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.133, 2/14/2013

Specialty Matched Consultant Advisory Panel – 11/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.133, 10/9/2014

Specialty Matched Consultant Advisory Panel – 11/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.133, 9/10/2015

Specialty Matched Consultant Advisory Panel- 11/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.133, 3/10/2016

Specialty Matched Consultant Advisory Panel- 11/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.133, 9/14/2017

Specialty Matched Consultant Advisory Panel- 11/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.133, 9/13/2018

Specialty Matched Consultant Advisory Panel- 11/2018

## 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)
- 4/29/16 Updated Policy Guidelines. Reference added. (lpr)
- 12/30/16 Specialty Matched Consultant Advisory Panel review 11/30/2016. No change to policy intent. (lpr)
- 10/13/17 Reference added. (lpr)

# Microwave Tumor Ablation

12/15/17 Specialty Matched Consultant Advisory Panel review 11/29/2017. No change to policy statement. (lpr)

12/31/18 Specialty Matched Consultant Advisory Panel review 11/28/2018. Updated Description and Policy Guidelines sections. No change to policy statement. Reference added. HCPCS code C9751 added to Billing/Coding section effective 1/1/19. (lpr)

---

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.