Microwave Tumor Ablation

Effective: January 1, 2019

Next Review: November 2019
Last Review: December 2018

IMPORTANT REMINDER

DESCRIPTION

Microwave ablation (MWA) uses microwave thermal energy to create thermal coagulation and localized tissue necrosis. MWA is proposed as a treatment of tumors, palliate symptoms.

MEDICAL POLICY CRITERIA

Note: This policy does not address liver tumors (primary or metastatic). See Cross References.

Microwave ablation is considered **investigational** as a treatment of primary and metastatic tumors, including but not limited to tumors of the breast, lung, and kidney.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. Radioembolization, Transarterial Embolization (TAE), and Transarterial Chemoembolization (TACE), Medicine, Policy No. 140
2. Radiofrequency Ablation (RFA) of Tumors Other than Liver, Surgery, Policy No. 92
3. Cryosurgical Ablation of Miscellaneous Solid Organ and Breast Tumors. Surgery, Policy No. 132
4. Magnetic Resonance (MR) Guided Focused Ultrasound (MRgFUS) and High Intensity Focused Ultrasound (HIFU) Ablation, Surgery, Policy No. 139

5. Ablation of Primary and Metastatic Liver Tumors, Surgery, Policy No. 204

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, 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 may have some advantages. 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 grounding pads be used during the procedure to prevent skin burns. Unlike radiofrequency ablation, MWA does not produce electric noise, which allows ultrasound guidance to occur during the procedure without interference. Finally, MWA can be completed in less time than radiofrequency ablation since multiple antennas can be used simultaneously.

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

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™

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

EVIDENCE SUMMARY

The principal health outcomes associated with treatment of malignancies are typically measured in units of survival past treatment: disease-free survival (DFS), a period of time following treatment where the disease is undetectable; progression-free survival (PFS), the duration of time after treatment before the advancement or progression of disease; and overall survival (OS), the period of time the patient remains alive following treatment.

In order to understand the impact of microwave ablation (MWA) on these outcomes, well-designed randomized controlled trials (RCTs) are needed that compare this therapy with standard medical and/or surgical treatment of primary and metastatic tumors.

BREAST

SYSTEMATIC REVIEWS

A 2017 systematic review of imaging-guided breast cancer treatments by Mauri compared technical success, efficacy, and complications.[1] 1,156 patients and 1,168 lesions were included in the analysis. The results showed that the microwave technique had the lowest technical success (93%) amongst the techniques that were analyzed including laser (98%), HIFU (96%), radiofrequency (96%), and cryoablation (75%). Additionally, there were significant differences and heterogeneity in the technical efficacy of the methods used.

A 2010 review of ablation techniques by Zhao for breast cancer found only 0-8% of breast tumors were completely ablated with microwave ablation (MWA).[2] The authors noted that studies identified for the review were mostly feasibility and pilot studies conducted in research settings.

NONRANDOMIZED STUDIES

In 2012, W. Zhou and colleagues reported on 41 patients treated with MWA directly followed by mastectomy for single breast tumors with a mean volume of 5.26 cm + 3.8 (range, 0.09 to 14.14 cm).[3] Complete tumor ablation was found by microscopic evaluation in 37 of the 41 tumors ablated (90%; 95% confidence interval [CI]: 76.9-97.3%). Reversible thermal injuries to the skin and pectoralis major muscle occurred in 3 patients. Results from this study should be met with caution due to its small sample size and lack of comparison group.

LUNG

RANDOMIZED CONTROLLED TRIAL

In a 2017 RCT published by Macchi, 52 patients were randomized into a radiofrequency ablation group or a microwave ablation group.[4] Within each group, the technical and clinical success were measured along with survival and complication rates. The radiofrequency ablation group saw significant reduction in tumor size between 6 and 12 months and the microwave ablation group saw a significant reduction in tumor size from pre-therapy to 12 months including from 6-12 months. There was no significant difference in survival between the groups. The authors reported that the microwave ablation group experienced less pain than the radiofrequency ablation group (p=0.0043).

NONRANDOMIZED STUDIES

In 2016, Vogl evaluated local tumor control, time to tumor progression, and survival rates among patients with lung metastatic colorectal cancer who underwent ablation therapy (N=109) performed using laser-induced thermotherapy (LITT), radiofrequency ablation (RFA), or microwave ablation (MWA).[5] Twenty-one patients underwent LITT (31 ablations), 41 patients underwent RFA (75 ablations), and 47 patients underwent MWA (125 ablations). Local tumor control was achieved in 17 of 25 lesions (68.0%) treated with LITT, 45 of 65 lesions (69.2%) treated with RFA, and 91 of 103 lesions (88.3%) treated with MWA. The progression-free survival rate at 1, 2, 3, and 4 years was 96.8%, 52.7%, 24.0%, and 19.1%, respectively, for patients who underwent LITT; 77.3%, 50.2%, 30.8%, and 16.4%, respectively, for patients who underwent RFA; and 54.6%, 29.1%, 10.0%, and 1.0%, respectively, for patients who underwent MWA, with no statistically significant difference noted among the three ablation methods.

In 2015, Acksteiner and Steinke reported a retrospective study that evaluated the safety, effectiveness, and follow-up imaging of MWA in 10 patients (age range, ≥75 years) with early-stage non-small-cell lung cancer (NSCLC).[6] Follow-up with CT and 18-fluorodeoxyglucose-positron emission tomography (FDG-PET) extended for 30 months (median, 12 months). No periprocedural deaths or major complications were reported. Seven patients were disease-free. Three patients showed growth of the treated lesions, 1 patient died (age 90) due to unknown cause 18 months postsurgery. One patient still living presented with local progression and disseminated metastatic disease at 12 months. One patient showed increasing soft tissue mass at the ablation site 15 months posttreatment, but 3 consecutive core biopsies over 2 months failed to confirm tumor recurrence.

A 2015 observational study evaluated the clinical efficacy and utility of percutaneous microwave ablation therapy (PMAT) for lung cancer without surgical treatment.[7] Thirty-nine lesions in 29 patients with peripheral lung cancer were treated by PMAT under local anesthesia. Treatments were completed in 29 patients. Average surgical time was 8 minutes (range, 5-12 minutes). Eight, 14, 4, and 3 patients achieved complete remission, partial remission, stable status, and progression, respectively, for an effectiveness rate of 76%. Complications included 5, 2, and 15 cases of pneumothorax, pleural effusion, and fever, respectively. No complications from needle track insertion were observed. Mean progression-free survival was 15 months. One- and 2-year OS rates were 91% and 83%, respectively.

Other evidence regarding MWA for lung tumors is limited to several nonrandomized retrospective studies.[8-16] These studies are all limited by lack of comparison group and small sample size. One study was also limited by short-term follow-up.[11] In addition, one small comparative study was published by Wei and colleagues in 2015, which compared MWA with chemotherapy (n=46) to chemotherapy alone (n=28) in patients with untreated stage IIIB or IV NSCLC.[17] PFS was reported to be significantly longer in the MWA/chemo group 10.9 months vs. 4.8 months (p=0.001). Overall survival tended to favor the MWA/chemo group although results were not statistically significant. Adverse events associated with MWA were observed in 67.4% of patients. Larger studies with a randomized design are needed to isolate the effect of MWA upon PFS and OS in patients with lung cancer.

PRIMARY RENAL TUMORS

SYSTEMATIC REVIEWS

In a 2014 systematic review and meta-analysis, Katsanos compared thermal ablation (MWA and RFA) with surgical nephrectomy for small renal tumors (mean size 2.5 cm).[18] Included in the analysis were 1 randomized study[19] on MWA and 5 cohort studies on RFA with a total of 587 patients. In the ablation group, the complication rates and renal function decline were significantly lower than in the nephrectomy group (p=0.04 and p=0.03, respectively). The local recurrence rate was 3.6% in both groups (risk ratio=0.92, 95% CI, 0.4 to 2.14, p=0.79) and disease-free survival up to 5 years was not significantly different between groups (hazard ratio=1.04, 95% CI, 0.48 to 2.24, p=0.92). The authors indicated additional RCTs were needed to compare MWA to nephrectomy and other ablative techniques.

Martin (2013) reported on a meta-analysis of MWA versus cryoablation for small renal tumors in 2013.[20] Included in the analysis were 7 MWA studies (n=164) and 44 cryoablation studies (n=2989). The studies were prospective or retrospective, nonrandomized, noncomparative studies. The mean follow-up duration was shorter for MWA than cryoablation (17.86 months vs 30.22 months, p=0.07). While the mean tumor size was significantly larger in the MWA studies than the cryoablation studies (2.58 cm vs 3.13 cm, respectively, p=0.04), local tumor progression (4.07% vs 2.53%, respectively; p=0.46), and progression to metastatic disease (0.8% vs 0%, respectively; p=0.12) were not significantly different.

RANDOMIZED CONTROLLED TRIALS

In 2012, Guan reported on a prospective randomized study to compare the use of MWA to partial nephrectomy (the gold standard of nephron-sparing surgical resection) for solitary renal tumors less than 4 cm.[19] Forty-eight patients received MWA and 54 had partial nephrectomy. Patients in the MWA group had significantly fewer postoperative complications than the partial nephrectomy group (6 [23.5%] vs. 18 [33.3%]; p=0.0187). MWA patients also had significantly less postoperative renal function declines (p=0.0092) and estimated perioperative blood loss (p=0.0002) than partial nephrectomy patients. At last follow-up, estimated glomerular filtration rate declines in both groups were similar (p=1.0000). Disease-specific deaths did not occur and overall local recurrence-free survival by Kaplan-Meier estimates at 3 years were 91.3% for MWA and 96.0% for partial nephrectomy (p= 0.5414). Studies with longer follow-up are needed in order to assess the benefits of MWA compared to nephrectomy.

NONRANDOMIZED STUDIES

Evidence regarding MWA treatment in patients with primary renal tumors primarily consists of several nonrandomized case studies, all of which are limited by lack of comparison and small sample size.[21-26] In addition, one study was also limited by short-term follow-up.[22]

OTHER TUMORS OR CONDITIONS

Nonrandomized studies of MWA for other indications are limited by lack of comparison group. Examples of other indications include adrenal carcinoma,[27] benign thyroid tumors,[28] pancreatic cancer[29], and other non-oncologic conditions (e.g., bleeding peptic ulcers, esophageal varices, secondary hypersplenism).

PRACTICE GUIDELINE SUMMARY

NATIONAL COMPREHENSIVE CANCER NETWORK (NCCN)

Neuroendocrine Tumors

In the NCCN guidelines on neuroendocrine tumors, MWA is listed as one treatment option (along with radiofrequency ablation or cryoablation) for liver metastases as hepatic regional therapy in carcinoid tumors and pancreatic endocrine (islet cell) tumors when there is unresectable disease and/or distant metastases.[30] These guidelines note, currently, there are limited prospective data and no randomized clinical trials on ablative therapies (including MWA), and data on these ablative techniques are emerging. Additionally, the 2 articles cited in the guideline on ablative techniques are not specific to MWA [category 2B: Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate].

AMERICAN COLLEGE OF CHEST PHYSICIANS (ACCP)

The ACCP evidence-based guidelines on the treatment of non-small cell lung cancer note the role of ablative therapies in the treatment of high-risk patients with stage I non-small cell lung cancer (NSCLC) is evolving. However, the ACCP does not recommend MWA for patients with NSCLC.[31]

AMERICAN COLLEGE OF RADIOLOGY (ACR)

The ACR radiologic management of hepatic malignancy (2015) rates appropriateness of thermal ablation treatment for seven clinical scenarios.[32] Thermal ablation typically refers to RFA, though may include cryoablation and microwave ablation. Only two studies were cited in the discussion regarding the potential benefits of MWA.

SUMMARY

For patients with tumors, it appears that microwave ablation (MWA) may improve health outcomes, though more research is needed to know for sure. Clinical practice guidelines based on research make recommendations for thermal ablative therapies without specifically specifying MWA over other options. Therefore, MWA is considered investigational as a treatment of tumors.

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CODES

Codes	Number	Description
CPT	19499	Unlisted procedure, breast
	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
	32999	Unlisted procedure, lungs and pleura
	38589	Unlisted laparoscopy procedure, lymphatic system
	49999	Unlisted procedure, abdomen, peritoneum and omentum
	50592	Ablation, renal tumor(s), unilateral, percutaneous, radiofrequency
	53899	Unlisted procedure, urinary system
	60699	Unlisted procedure, endocrine system
HCPCS	C9751	Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3-d rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (ebus) guided transtracheal and/or transbronchial sampling (eg, aspiration[s]/biopsy[ies]) and all mediastinal and/or hilar lymph node stations or structures and therapeutic intervention(s)

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