

# Regence

Medical Policy Manual

Surgery, Policy No. 189

## ***Microwave Tumor Ablation***

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### **IMPORTANT REMINDER**

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

### **DESCRIPTION**

Microwave ablation (MWA) uses microwave thermal energy to create thermal coagulation and localized tissue necrosis. MWA is proposed for treating tumors, controlling local tumor growth and palliating symptoms.

### **MEDICAL POLICY CRITERIA**

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

- I. Microwave ablation may be considered **medically necessary** to treat tumors when one or more of the following criteria are met:
  - A. Isolated peripheral non-small cell lung cancer (NSCLC) lesion that is no more than 3 cm in size when both of the following criteria are met:
    1. Surgical resection or radiation treatment with curative intent is considered appropriate based on stage of disease, however, medical co-morbidity renders the individual unfit for those interventions; and
    2. Tumor is located at least 1 cm from the trachea, main bronchi, esophagus, aorta, aortic arch branches, pulmonary artery and the heart.

- B. Malignant non-pulmonary tumor(s) metastatic to the lung that are no more than 3 cm in size when all of the following criteria (1. – 3.) are met:
1. In order to preserve lung function when surgical resection or radiation treatment is likely to substantially worsen pulmonary status, or the patient is not considered a surgical candidate; and
  2. There is no evidence of extrapulmonary metastases; and
  3. The tumor is located at least 1 cm from the trachea, main bronchi, esophagus, aorta, aortic arch branches, pulmonary artery and the heart.
- II. Microwave ablation is considered **investigational** as a technique for ablating all other benign or malignant tumors other than liver tumors that do not meet the policy criteria above.

*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 to 3 cm elliptical area (5 x 3 cm) of tissue ablation. In tumors greater than 2 cm in diameter, 2 to 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 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 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 (see Cross References).

## **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 are selected microwave ablation devices that have 510(k) clearance for MWA of (unspecified) soft tissue:

- BSD Medical Corporation’s MicroThermX® Microwave Ablation System (MTX-180);
- Microsulis Holdings Ltd’s Acculis Accu2i;
- MedWaves Microwave Coagulation/Ablation System;
- Covidien’s Emprint™ Ablation System and Emprint™ SX Ablation Platform with Thermosphere™ Technology;
- Angiodynamics’ Solero Microwave Tissue Ablation System;
- Surgnova Healthcare Technologies’ Microwave Ablation System; and
- Johnson & Johnson’s NEUWAVE Microwave Ablation System

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.<sup>[1]</sup> 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 to 8% of breast tumors were completely ablated with microwave ablation (MWA).<sup>[2]</sup> The authors noted that studies identified for the review were mostly feasibility and pilot studies conducted in research settings.

#### NONRANDOMIZED STUDIES

Yang (2020) published a prospective multicenter study of MWA for the treatment of benign breast lesions.<sup>[3]</sup> A total of 440 patients with clinicopathologically confirmed benign breast lesions were treated with MWA and evaluated for technical success, complications, volume reduction ratio (VRR), palpability, and cosmetic satisfaction. In the 755 treated lesions (mean maximum diameter  $1.7 \pm 0.6$  cm), complete ablation was achieved in 100%. The median follow-up was 13.7 months. The 12-month VRR was 97.9% for all lesions, 98.6% for 1.0- to 2.0-cm lesions, and 96.9% for  $\geq 2.0$ -cm lesions. The percent of palpable lesions went from 85.7% pre-treatment to 55.9% post-treatment. Patients rated the cosmetic and minimally invasive satisfaction rates as good or excellent in 98.4% and 94.5% of cases, respectively.

Yu (2020) reported a small cohort study comparing MWA with nipple-sparing mastectomy for invasive ductal carcinoma of the breast.<sup>[4]</sup> A total of 21 MWA-treated and 43 nipple sparing mastectomy-treated patients were retrospectively enrolled. The mean age of the MWA-treated patients was 24 years older than that of the nipple sparing mastectomy patients. Median follow-up was 26.7 months (range, 14.6 to 62.5 months). Technical effectiveness was 100%. No significant differences between groups in tumor progression were identified ( $p=0.16$ ).

In 2012, Zhou reported on 41 patients treated with MWA directly followed by mastectomy for single breast tumors with a mean volume of  $5.26 \text{ cm} + 3.8$  (range, 0.09 to 14.14 cm).<sup>[5]</sup>

Complete tumor ablation was found by microscopic evaluation in 37 of the 41 tumors ablated (90%; 95% CI 76.9 to 97.3%). Reversible thermal injuries to the skin and pectoralis major muscle occurred in three patients. Results from this study should be met with caution due to its small sample size and lack of comparison group. The MWA group had significantly lower hospitalization time ( $p < 0.001$ ) and better cosmetic results ( $p < 0.001$ ). No major complications occurred.

## LUNG

### SYSTEMATIC REVIEWS

Laeseke (2023) conducted a systematic review and meta-analysis that compared the efficacy of image guided thermal ablation, including MWA, to stereotactic body radiation therapy (SBRT) in patients with stage IA NSCLC among studies with at least 40 patients.<sup>[6]</sup> Comparative and single-arm studies, as well as single treatments from comparative studies were included in the meta-analysis. Studies that enrolled patients with recurrent NSCLC, or that used interventions as salvage treatments, were excluded. Key outcomes of interest were local tumor progression, overall survival, and disease-free survival. 40 image-guided thermal ablation study-arms ( $n=2,691$  patients) and 215 SBRT study-arms ( $n=54,789$  patients) were identified. Local tumor progression was lowest after SBRT at years one and two in single-arm pooled analyses (4% and 9% versus 11% and 18%) and at one year in meta-regressions when compared to ablative therapies (odds ratio [OR]=0.2, 95% CI = 0.07 to 0.63). Microwave ablation patients had the highest disease-free survival of all treatments in single-arm pooled analyses. In meta-regressions at two and three years, disease-free survival was significantly lower for radiofrequency ablation compared to MWA (OR=0.26, 95% CI = 0.12 to 0.58; OR=0.33, 95% CI = 0.16 to 0.66, respectively). Overall survival was similar across treatment types and time points. Older age, male patients, larger tumors, retrospective studies, and non-Asian study region were predictors of worse clinical outcomes. Among high quality studies, stage IA microwave ablation patients had lower local tumor progression, higher overall survival, and generally lower disease-free survival, compared to the main analysis of all NSCLC patients.

Chan (2021) reported a systematic review and meta-analysis comparing survival outcomes for surgical resection versus CT-guided percutaneous ablation (RFA and MWA) for stage 1 non-small cell lung cancer (NSCLC).<sup>[7]</sup> A total of eight studies with 792 patients met inclusion criteria. The difference between groups for one- to five-year overall survival (OS) and cancer-specific survival (CSS) and three- and five-year disease-free survival (DFS) were not statistically significant. However, differences between groups in one- and two-year DFS were statistically significant, favoring sublobar resection (OR 2.22, 95% CI 1.14 to 4.34; OR 2.60, 95% CI 1.21 to 5.57 respectively). According to a subgroup analysis, there was no significant difference in OS between lobectomy and MWA, but one- and two-year OS were significantly better in those treated with sublobar resection (wedge resection or segmentectomy) versus RFA (OR 2.85, 95% CI 1.33 to 6.10; OR 4.54, 95% CI 2.51 to 8.21, respectively).

Nelson (2019) included 12 retrospective observational studies of MWA in patients with primary or metastatic lung tumors.<sup>[8]</sup> The reviewers did not pool results due to clinical and methodological heterogeneity across the studies. The studies varied with regard to patient characteristics (tumor size, histology, number of treated nodules), outcome measures, and technical experience of surgeons performing the procedures. The primary outcome was local recurrence, and survival outcomes were not assessed. Overall, local recurrence rates ranged

from 9% to 37% across the studies. Newer reports and those that targeted smaller tumors showed more favorable efficacy rates. Results in patients with multiple tumors were not reported separately. Four studies reported results by tumor size; the local recurrence rate for large tumors (> 3 or 4cm depending on the study) were 50%, 75%, 36%, and 26%. In the same four studies, for small tumors (<3 or 3.5 cm depending on the study), local recurrence rates were 19%, 18%, 18%, and 5%, respectively. The most frequent adverse event with MWA was a pneumothorax requiring a chest tube. The reviewers concluded that MWA may be a useful tool in selected patients who are not ideal surgical candidates.

In a meta-analysis of observational studies, Yuan (2019) found higher overall survival for patients who received RFA compared to those who received MWA.<sup>[9]</sup> However, these estimates were not directly comparable because they came from different sets of studies, and the reviewers concluded that percutaneous RFA and MWA were both effective with a high safety profile. The studies used different patient eligibility criteria (e.g., tumor size, lesion number, age, follow-up). Subgroup analyses by tumor size or tumor number were not possible from the data reported.

Jiang (2018) conducted a network meta-analysis to determine the effectiveness of different ablation techniques in patients with lung tumors.<sup>[10]</sup> Tumor size, stage of disease, and primary versus metastatic disease were not accounted for in the analysis. For MWA, weighted average overall survival rates were 82.5%, 54.6%, 35.7%, 29.6%, and 16.6% at one, two, three, four, and five years, respectively. According to the meta-analysis, RFA and MWA were more effective in decreasing the progression rate of lung malignancies than cryoablation (OR 0.04, 95% CI 0.002 to 0.38,  $p=0.005$  and OR 0.02, 95% CI 0.002 to 0.24,  $p=0.001$ , respectively). Major complications were not significantly different between RFA, MWA, and cryoablation ( $p>0.05$ ).

## **RANDOMIZED CONTROLLED TRIAL**

In a 2017 RCT published by Macchi, 52 patients were randomized into a radiofrequency ablation group or a microwave ablation group.<sup>[11]</sup> 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 to 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**

Hu (2020) reported a retrospective comparison of wedge resection and microwave ablation as a first-line treatment of stage I NSCLC.<sup>[12]</sup> A total of 223 consecutive patients with T1N0 NSCLC received first-line treatment either using wedge resection ( $n=155$ ) or MWA ( $n=68$ ). A propensity matched analysis, which yielded 56 pairs of patients, identified no significant differences in three- or five-year PFS (MWA 54.0% and 36.0%, respectively; wedge resection 66.0% and 56.0%, respectively;  $p=0.029$ ) or OS (MWA 60.0% and 55.0%; wedge resection 81.0% and 72.0%, respectively;  $p=0.031$ ). According to a subgroup analysis, local recurrence and PFS for NSCLCs that were contiguous to the pericardium were better in the wedge resection group than in the MWA group ( $p<0.05$ ).

Das (2020) performed a retrospective analysis to compare the safety and efficacy of cryoablation and MWA for the treatment of NSCLC.<sup>[13]</sup> Patients who were treated with microwave ablation (n=56) or cryoablation (n=45) for stage IIIB or IV NSCLC were included. The primary endpoint was PFS, which was not significantly different between groups (10 months for cryoablation versus 11 months for MWA; p=0.36). The secondary endpoints were OS (27.5 months for cryoablation versus 18 months for MWA; p=0.07) and adverse events (p>0.05). Dividing the group by tumor size showed that for large tumors (>3 cm; p=0.04), but not for small tumors (≤3 cm; p0.79), the microwave ablation group had significantly longer median PFS.

Aufranc (2019) reported the efficacy and complication rate of cryoablation and MWA for the treatment of primary and secondary lung tumors.<sup>[14]</sup> The authors performed a retrospective analysis of 115 patients with primary (n=41) or secondary (n=119) lung tumors. Mean overall follow-up was 488 days. Ablation volumes, local recurrence, and mean length of hospital stay were not significantly different between groups at one month (24.1±21.7 cm<sup>3</sup> for RFA and 30.2±35.9 cm<sup>3</sup> for MWA; p=0.195; 6/79 in the radiofrequency group and 3/81 in the MWA group; p=0.049; 4.5±3.7 days for RFA and 4.7±4.6 days for MWA; p=0.76). However, the difference in pneumothoraces between groups was statistically significant (32/79 for radiofrequency and 20/81 for MWA; p=0.049).

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).<sup>[15]</sup> 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 one, two, three, and four 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.

Other evidence regarding MWA for lung tumors is limited to nonrandomized retrospective studies.<sup>[16-32]</sup> These studies all have limitations, including lack of comparison group, small sample size, short-term follow-up. 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

Wu (2023) published a systematic review and meta-analysis of MWA for the treatment of renal cell carcinoma and larger (T1b) tumors.<sup>[33]</sup> Among 27 studies and 1584 patients with malignant renal tumors, pooled technical success and efficacy rates were 99.6% (95% confidence interval [CI], 98.0% to 100%) and 96.2% (95% CI, 93.8% to 98.2%), respectively. Local recurrence rate was 3.2% (95% CI, 1.9%-4.7%). At one, three, and five years, overall survival rates were 99.0% (95% CI, 97.5% to 99.9%), 96.0% (95% CI, 93.1% to 98.3%), and 88.1% (95% CI, 80.3% to 94.2%). In 204 patients with T1b tumors, pooled technical success and efficacy rates were 100% (95% CI, 96.6% to 100%) and 85.2% (95% CI, 71.0% to 95.8%). Local recurrence rate was 4.2% (95% CI, 0.9% to 8.9%). At one and three years, overall

survival rates were 94.3% (95% CI, 85.7% to 99.6%) and 89.3% (95% CI, 68.7% to 100%). Review authors concluded that MWA yielded favorable short- to intermediate-term oncologic outcomes with low complication rates.

Uhlig (2019) published a systematic review with meta-analyses to compare partial nephrectomy, radiofrequency ablation, cryoablation and microwave ablation and the effect on oncologic, perioperative and functional outcomes in studies published from 2005 to 2017.<sup>[34]</sup> Microwave ablation was a treatment in 344 of 24,077 patients and represented in 6 of 47 studies. The review included the single RCT (Guan 2012, described below) which is the only study with results for all three outcomes of interest. No new data was included but the review utilized a network meta-analyses technique. Microwave ablation when compared to partial nephrectomy, the comparator of interest, was reported to have a lower procedural complication rate but higher local recurrence and cancer-specific mortality rates.

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).<sup>[35]</sup> Included in the analysis were one randomized study<sup>[36]</sup> on MWA and five 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 five 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.<sup>[37]</sup> Included in the analysis were seven 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.<sup>[36]</sup> 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 three 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**

Yu (2022) reported long-term follow-up of 323 consecutive patients with T1N0M0 renal cell carcinoma who underwent MWA.<sup>[38]</sup> Patients were analyzed by stage. A total of 275 cT1a

patients were followed for a median of 66.0 months (interquartile range [IQR] 58.4 to 73.6). In these patients, 10-year local neoplastic processes, cancer-specific survival, disease-free survival, and overall survival rates were 1.9%, 87.4%, 71.8, and 67.5%, respectively. A total of 48 cT1b patients were followed for a median of 30.4 months (IQR, 17.7 to 44.8). In these patients, five-year local tumor progression, cancer-specific survival, disease-free survival, and overall survival rates were 11.3%, 91.4%, 69.1, and 89.2%, respectively. Major complications were 3.5% in cT1a patients and 6.9% in cT1b patients.

Vanden Berg (2021) reported a case series of 101 patients with renal tumors treated with MWA.<sup>[39]</sup> All ablation procedures were performed by a single board-certified urologist/interventional radiologist. Median tumor size was 2.0 cm (IQR 1.5 to 2.6). All patients achieved technical success. All patients but one were discharged on the day of the procedure. Two Clavien-Dindo type-I complications, one type-II complication, and one type-III complication were reported. At a median radiographic follow-up of 376.5 days, two tumors had recurred.

John (2020) published a prospective case series of 113 patients treated with MWA for renal cell carcinoma.<sup>[40]</sup> The median tumor diameter was 25 mm (IQR 20 to 32 mm) and median follow-up was 12 months. One patient (0.9%) had local recurrence, which was treated with re-ablation. Two patients developed metastatic progression, one had a lung nodule at follow-up, and one had a possible local recurrence. Associations were identified between post-procedure complications and total ablation time (OR 1.152/min, 95% CI 1.040 to 1.277) and total ablation energy (OR 1.017/kJ, 95% CI 1.001 to 1.033).

An (2020) published a retrospective review of 114 patients with renal cell carcinoma who were treated with MWA.<sup>[41]</sup> Patients were divided by tumor location, either central (n=44) or peripheral (n=70). No significant differences were found between locations (17.7% vs. 11.7%, p=0.34) for overall adverse event rate or Grade II or higher adverse event rate (7.8% vs. 2.6%, p = 0.17). There was a statistically significant difference in rate of adjunctive maneuvers of hydrodissection and/or pyeloperfusion (53% for central tumors vs. 29% for peripheral tumors, p=0.006).

Acosta Ruiz (2020) reported the results of another retrospective review of MWA for renal tumors.<sup>[42]</sup> Ninety-three patients with 105 tumors were treated with CT-guided MWA. The median tumor size was 25 mm. The primary efficacy rate was 92.2%. Periprocedural complications occurred in 5.2% of sessions (four Clavien-Dindo I and one Clavien-Dindo IIIa) and one postprocedural Clavien-Dindo II complication was reported.

Guo (2021) reported a retrospective review of 106 patients with 119 T1a renal cell carcinoma tumors treated with MWA.<sup>[43]</sup> Complete response was achieved in 95.3% of patients (mean tumor diameter, 2.4 cm; range, 1 to 4 cm). Local tumor progression was observed in six patients at a mean of 20 months post-procedure. Local progression-free survival rates were 100%, 92.8%, and 90.6% at one, two, and three years, respectively. OS rates were 99%, 97.7%, and 94.6% at one, two, and three years respectively. Complications were reported in six patients (5.7%) within 30 days of the procedure, but none of these required intervention.

Aarts (2020) conducted another retrospective review of 100 patients with 108 T1 renal cell carcinomas treated with MWA.<sup>[44]</sup> The median tumor size in this study was 3.2 cm (interquartile range, 2.4 to 4 cm). Primary efficacy was achieved for 81% (88/108) of lesions overall, but primary efficacy rates were lower among patients with T1b tumors (52%) versus T1a tumors

(89%;  $p < 0.001$ ). Secondary efficacy was achieved for 97% (101/103). Over a median follow-up time of 19 months, local tumor recurrence was observed for 4 (4%) tumors.

Shapiro (2020) compared outcomes in patients with clinical T1b renal cell carcinoma treated with MWA, partial nephrectomy, or radical nephrectomy.<sup>[45]</sup> A retrospective analysis was completed of 40 MWA, 74 partial nephrectomy, and 211 radical nephrectomy patients. Median follow-up was 34, 35, and 49 months for MWA, partial nephrectomy, and radical nephrectomy, respectively. The decrease in post-treatment estimated glomerular filtration rate was significantly greater in radical nephrectomy patients (29%,  $p < 0.001$ ) than partial nephrectomy (3.2%) or microwave ablation (4.5%). The local recurrence rates were 5%, 1.4%, and 0.5% in the MWA, partial nephrectomy, and radical nephrectomy treatment groups, respectively. The estimated five-year local recurrence-free survival rates were 94.5%, 97.9%, and 99.2% for the MWA, partial nephrectomy, and radical nephrectomy treatment groups, respectively. Although the estimated five-year local recurrence-free survival rate was significantly lower for the MWA group, after a univariable Cox regression, local recurrence was not associated with microwave ablation treatment.

De Cobelli (2019) performed a retrospective evaluation of the comparative safety and effectiveness of cryoablation and MWA for the treatment of T1a renal tumors.<sup>[46]</sup> T1a renal cancer patients with either a contraindication to surgery or a refusal of surgery were treated at a single center for with either cryoablation ( $n=44$ ) or MWA ( $n=28$ ). Median follow-up was 20 and 22 months, for cryoablation and MWA, respectively. Technical success, defined as the absence of arterial enhancement in the ablation zone at the one-month cross-sectional imaging, was not significantly different between groups (92% vs. 94% for cryoablation and MWA, respectively;  $p=0.8$ ), nor was the occurrence of complications (cryoablation 5/51, MWA 2/32;  $p=0.57$ ), or disease recurrence (cryoablation 3/47, MWA 1/30;  $p=0.06$ ). The median procedure time was significantly lower in the MWA group (110 min. and 40 min. for cryoablation and MWA, respectively;  $p=0.003$ ).

Zhou (2019) compared the outcomes following three ablation techniques for the treatment of T1a biopsy-proven renal cell carcinoma.<sup>[47]</sup> A total of 297 patients were treated with radiofrequency ablation ( $n=244$ ), cryoablation ( $n=26$ ), and MWA ( $n=27$ ). They were retrospectively assessed for adverse events, treatment efficacy, and therapeutic outcomes. Technical success rates were not significantly different between groups ( $p=0.33$ ). The authors reported that primary efficacy one month following ablation was more likely following RF ablation and MW ablation than cryoablation. At the two-year follow-up, there were no reports of local recurrence, metastatic progression, or renal cell carcinoma-related deaths in any treatment group. Also at two years, there was also no significant change in estimated glomerular filtration rate compared with baseline ( $p=0.71$ ).

Additional 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.<sup>[48-55]</sup> In addition, one study was also limited by short-term follow-up.<sup>[49]</sup>

## OTHER TUMORS OR CONDITIONS

Wu (2022) conducted a systematic review and meta-analysis comparing MWA versus conventional surgery for the treatment of papillary thyroid microcarcinoma.<sup>[56]</sup> There were 13 included studies which were all non-randomized. There was no differences between the 2 groups in recurrence rate or lymph node metastasis; however, the MWA group did have a

shorter operation time, less intra-operative blood loss, shorter postoperative hospital stay, and few complications.

Nonrandomized studies of MWA for other indications are limited by lack of comparison group. Cui (2019) conducted a non-comparative systematic review and meta-analysis of five retrospective studies and two prospective studies in patients with benign thyroid nodules or papillary thyroid microcarcinoma and found that MWA improved nodule volume and symptom scores in these patients.<sup>[57]</sup> More recent studies also lack control groups or do not compare to standard of care.<sup>[58-61]</sup>

Examples of other indications include adrenal carcinoma,<sup>[62, 63]</sup> oligometastases,<sup>[64]</sup> bone tumors,<sup>[65-68]</sup> thyroid carcinoma,<sup>[69, 70]</sup> pancreatic cancer,<sup>[71]</sup> sinus mucoceles,<sup>[72]</sup> and other non-oncologic conditions (e.g., bleeding peptic ulcers, esophageal varices, secondary hypersplenism, myomas).

## PRACTICE GUIDELINE SUMMARY

### NATIONAL COMPREHENSIVE CANCER NETWORK

National comprehensive cancer network (NCCN) guidelines for non-small cell lung cancer (v4.2023) recommend “image-guided thermal ablation (e.g., cryotherapy, microwave, radiofrequency [as] an option for select patients.”<sup>[73]</sup> image-guided thermal ablation therapy is considered an option for the management of NSCLC lesions <3 cm as ablation for NSCLC lesions >3 cm has been associated with higher rates of local recurrence and complications.

### AMERICAN COLLEGE OF CHEST PHYSICIANS

The American College of Chest Physicians (ACCP) 2013 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.<sup>[74]</sup>

## SUMMARY

Surgical resection is the treatment of choice for primary non-small cell lung cancer (NSCLC) or metastatic tumors in the lung. For those patients who are unable to tolerate surgery, microwave ablation (MWA) may be a treatment option in certain cases. While available studies are limited by study design, accumulating evidence suggests that MWA may be similar to surgery in survival rates, and rates of procedure-related complications and mortality. Therefore, in patients with NSCLC or metastatic tumors in the lung who are ineligible for surgical treatment, MWA may be considered medically necessary when the policy criteria are met.

For patients with tumors that do not meet policy criteria, it appears that microwave ablation (MWA) may improve health outcomes, though more research is needed to know for sure. Therefore, MWA is considered investigational as a treatment of these 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)

**Date of Origin:** October 2013