# Molina Clinical Policy
# Microwave Ablation of Lung and Liver Tumors: Policy No. 427

**Last Approval: 12/11/2024**
**Next Review Due By: December 2025**

## DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

## OVERVIEW

**Lung cancer and liver cancer** will see approximately 234,000 and 41,000 new cases diagnosed in 2024, respectively, according to the American Cancer Society (2024). Treatment options are based on staging, resectability, presence of comorbidities, and performance status. There are a variety of treatment modalities for both lung and liver tumors, with surgical intervention being the gold standard; however, not all patients are surgical candidates. Non-surgical treatments include thermal ablation therapy, chemotherapy, radiation therapy, embolization therapy, target drug treatments, and immunotherapy. Tumor ablation refers to the destruction of tumors without their removal and are generally classified as chemical ablation, thermal ablation, irreversible electroporation, or external-energy-delivery-based ablation. Thermal ablation modalities include radiofrequency ablation, cryoablation, microwave ablation, and laser ablation.

**Microwave ablation,** also known as microwave coagulation therapy, is a percutaneous ablation modality based on heat induction via an electromagnetic field surrounding the needle, which acts as an antenna to stimulate water molecules, resulting in a faster and more uniform heating of the tissue and the death of cells via coagulation necrosis. Microwave ablation is similar to radiofrequency or cryosurgical ablation; however, in microwave ablation, the heating process is active, resulting in temperatures that are higher than radiofrequency ablation and the technique allows for multiple ablations to be performed simultaneously allowing for faster ablation times due to larger ablation zones, and a reduced heat sink effect compared to radiofrequency ablation (Curley et al. 2024).

Microwave ablation is used to treat tumors that are deemed inoperable, unresectable, or in patients who are deemed surgically ineligible due to age or the presence of comorbidities. It can be performed openly, laparoscopically, percutaneously, or thoracoscopically under sedation, local, or general anesthesia. After identifying the tumor, the rendering provider uses guided imagery to insert a small needle with a probe directly into the tumor. Following probe placement confirmation, a microwave antenna or multiple antennas are connected to a generator, which then generates tumor friction and local heat coagulates nearby tissue, causing ablation. In tumors larger than 2 cm, several antennas may be utilized to increase the targeted area and reduce operative time. Generally, microwave ablated cells are replaced by fibrosis and scar tissue. If there is a local recurrence, it typically occurs at the margins and repeat treatment may be necessary. Microwave ablation therapy may limit local tumor growth and prevent recurrence, alleviate symptoms, and extend survival.

### Regulatory Status

The FDA has cleared multiple microwave ablation devices for marketing via the 510(k) process. To clear these devices, the FDA used determinations of substantial equivalence to existing radiofrequency and microwave ablation devices under the product code NEY.

Indications for use are labeled for soft tissue ablation, including partial or complete ablation of nonresectable liver tumors. Certain devices are specifically cleared for use in open surgical ablation, percutaneous ablation, or laparoscopic procedures.

The following devices have 510(k) clearance for microwave ablation of (unspecified) soft tissues (FDA 2024). This is not an all-inclusive list; refer to FDA site for a list of all devices cleared:

- BSD Medical's MicroThermX® Microwave Ablation System (MTX-180)
- MicroSurgeon's Microwave Soft Tissue Ablation System
- Microsulis Medical's (now part of AngioDynamics) Acculis® Accu2i
- NeuWave Medical's Certus 140™
- swiftPro™ System
- Valleylab's (subsidiary of Covidien) VivaWave® Microwave Ablation System
- Vivant's (acquired by Valleylab in 2005) Tri-Loop™ Microwave Ablation Probe

## RELATED POLICIES

This policy focuses on microwave ablation of primary or metastatic liver and lung tumors; it does not address other ablative therapies or microwave ablation for the treatment of splenomegaly, ulcers for cardiac applications, or as a surgical coagulation tool.

## COVERAGE POLICY

**A. Primary or Metastatic Hepatic Tumors**
Microwave ablation of primary or metastatic hepatic tumors may be **considered medically necessary** when **ALL** the following criteria are met:

1. The tumor is unresectable due to the location or extent of the lesion(s) and/or comorbid conditions, with documentation that the member is not an open surgical candidate or unable to tolerate an open surgical resection

2. A single tumor of ≤ 5 cm or up to 3 nodules ≤ 3 cm each

**B. Primary or Metastatic Lung Tumors**
Microwave ablation of primary or metastatic lung tumors may be **considered medically necessary** when **ALL** the following criteria are met:

1. The tumor is unresectable due to the location or extent of the lesion(s) and/or comorbid conditions, with documentation that the member is not an open surgical candidate or unable to tolerate an open surgical resection

2. A single tumor of ≤ 3 cm

**Limitations and Exclusions**

The following are considered **experimental, investigational, and unproven** based on insufficient evidence:

1. Any indications other than those listed above. Microwave ablation of primary or metastatic tumors other than liver or lung is considered experimental. There is insufficient evidence to support a conclusion about the health outcomes or benefits of these procedures.

**DOCUMENTATION REQUIREMENTS.** Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

## SUMMARY OF MEDICAL EVIDENCE

The current evidence for the microwave ablation therapy in patients with unresectable primary or metastatic solid tumors, other than hepatocellular or pulmonary, is insufficient. High-quality evidence, such as well-designed RCTs, comparative studies, and systematic reviews, with relevant outcomes in overall survival, symptoms, quality of life, and treatment-related mortality and morbidity, to conclude that the technology improves overall health outcomes.

### Unresectable Primary or Metastatic Hepatic Tumors

***Systematic Reviews and Meta-Analysis***

Zhang et al. (2023) conducted a systematic review and meta-analysis comparing microwave ablation to radiofrequency ablation in the treatment of hepatocellular carcinoma < 5 cm. Six studies met inclusion criteria, two randomized controlled trials and four propensity score cohort studies, for a total of 894 patients: 446 patients in the microwave ablation group and 448 patients in the radiofrequency ablation group. The objective of the analysis was to evaluate and compare recurrence-free survival rates, overall survival rates, and complication rates between the two ablation techniques. Due to the lack of included studies, the odds ratios of the random-effects model based on random effect model were applied to reduce the accuracy of effect estimation. Microwave ablation had higher reoccurrence free survival rates in the post-operative 1-, 2-, 3- and 5-year (OR = 0.58, 95% CI: 0.40, 0.84; OR = 0.60, 95% CI: 0.45, 0.80; OR = 0.56, 95% CI: 0.33, 0.93; and OR = 0.44, 95% CI: 0.30, 0.65). In three of the included studies radiofrequency ablation and microwave ablation overall survival rates were compared to reveal no significant difference in 1-, 2- and 3-year overall survival between the two groups; however, the overall survival of microwave ablation was significantly higher in 5 years after ablation (OR=0.48, 95% CI: 0.34, 0.68). The study had some limitations, such as, the accuracy of the results needs to be further verified due to the small number of studies included, and two of the six trials did not have a long-term follow-up period (<5 years). The authors concluded that percutaneous microwave ablation exhibited an advantage in improving prognosis in those with hepatocellular carcinoma < 5cm over radiofrequency ablation.

Shin et al. (2021) conducted a systematic review and meta-analysis comparing resection with local ablation (RFA, MWA, with or without TACE) for HCC in patients with HCC who met the Milan criteria. The analysis comprised 7 RCTs and 18 non-randomized trials (N=5629). Due to the absence of data, all non-randomized studies were assessed as having a high risk of bias. The meta-analysis concluded that OS was not significantly better with resection (HR for 5-year OS 0.85, 95% CI 0.55-1.29) but that both five-year relapse-free survival (HR 0.75, 95% CI 0.62-0.92) and local recurrence rates (HR 0.45, 95% CI 0.26-0.79) both favored surgeries. All studies were considered to have a risk of bias because of lack of information on randomization method, baseline imbalances between the two groups in important prognostic factors (e.g., Child-Pugh classification), or missing data.

***Non-Randomized Studies, Retrospective Reviews, and Other Evidence***

Ryu et al. (2022) conducted a retrospective study to analyze the outcomes in patients with intermediate stage hepatocellular carcinoma who underwent microwave ablation therapy. Two hundred and forty-six patients were analyzed for overall survival and recurrence free survival rate, and the Cox proportional hazard model was used to evaluate potential prognostic factors. The 1-, 3-, 5-, and 10-year overall survival rates were 98%, 74%, 51%, and 28%, respectively, with the 1-, 3-, 5-, and 10-year recurrence-free survival rates were 80%, 32%, 18%, and 10%, respectively. The major complication rate (Clavien-Dindo classification IIIa or above) was 7%, with no procedure-related mortality. Multivariate analysis identified beyond up-to-7 criteria (the sum of the largest tumor's diameter in cm and the total number of tumors), Child-Pugh grade B, and serum alpha-fetoprotein concentration ≥ 100 ng/mL as independent risk factors for overall survival after operative microwave ablation. The overall survival of patients within up-to-7 and Child-Pugh grade A was better than that of the remaining patients, 5-year overall survivals being 67% and 37%, respectively (P < 0.001). The analyses led the authors to conclude microwave ablation to be a safe and effective procedure in patients with intermediate stage hepatocellular carcinoma.

Wang Z et al. (2022) conducted a retrospective study to compare the effectiveness of microwave ablation versus laparoscopic liver resection on solitary hepatocellular carcinoma tumors 3 -5 cm. The multicenter study comprised of two cohorts, the 2008-2019 cohort with 335 participants in each group, and the 2014 -2019 cohort with 257 participants in each group, for a total of 1289 participants. Propensity score matching was used to balance all baseline variables between the two cohorts. For cohort 2008-2019, during a median follow-up of 35.8 months, there were no differences in overall survival between microwave ablation and laparoscopic liver resection (HR: 0.88, 95% CI 0.65-1.19, p =

0.420), and microwave ablation was found to have inferior disease-free survival rates to laparoscopic liver resection (HR 1.36, 95% CI 1.05-1.75, p = 0.017). For cohort 2014-2019, there was comparable overall survival (HR 0.85, 95% CI 0.56-1.30, p = 0.460) and disease-free survival rates, between microwave ablation and laparoscopic liver resection respectively, approached statistical significance (HR 1.33, 95% CI 0.98-1.82, p = 0.071). For both cohorts, microwave ablation exhibited shorter hospitalization stays, lower cost, and shared comparable major complications (both p > 0.05) leading to the author conclusion that microwave ablation may be a first line therapy alternative to laparoscopic liver resection for solitary 3-5-cm hepatocellular carcinoma in selected patients, especially for patients unsuitable for laparoscopic liver resection.

## Unresectable Primary or Metastatic Lung Tumors

***Systematic Reviews and Meta-Analyses***

Chan et al. (2021) conducted a systematic review and meta-analysis comparing microwave ablation to surgical resection in patients with non-small cell lung cancer. A total of eight studies were included, totaling 792 patients with 460 resections and 332 ablations. There were no significant differences in 1- to 5-year overall survival or cancer specific survival between surgery versus ablation; however, there were significantly better 1- and 2-year disease free rates for surgery over ablation (OR 2.22, 95% CI 1.14-4.34; OR 2.60, 95% CI 1.21-5.57 respectively). Subgroup analysis demonstrated no significant overall difference between lobectomy and microwave ablation. In the two studies which only included patients with stage 1A non-small cell lung cancer, pooled outcomes demonstrated no significant differences in 1- to 3-year overall survival or disease-free survival rates between surgery versus ablation. The authors concluded that while surgical resection is the gold standard, for patients who are not surgical candidates ablation offers comparable and promising overall survival and disease-free survival rates.

Nelson et al. (2019) conducted a systematic review to compile data on local recurrence and adverse events following microwave ablation for primary non-small cell lung cancer or pulmonary metastases. Twelve retrospective observational studies of microwave ablation in patients with primary or metastatic lung tumors were included in the review. Due to clinical and methodological differences between the studies, the reviewers did not pool the results. Patient characteristics (tumor size, histology, and the number of treated nodules), outcome measures, and the technical experience of the surgeons performing the procedures varied between studies. The primary outcome was local recurrence, with no regard for survival outcomes. Across the studies, local recurrence rates ranged from 9% to 37%. Higher efficacy rates were found in newer studies, as well as those focusing on smaller tumors. Patients with multiple tumors did not have their outcomes reported separately. The local recurrence rates for large tumors (> 3 or 4cm depending on the study) were 50%, 75%, 36%, and 26%, respectively, according to four studies. In the same four studies, the rates of local recurrence for small tumors (3 or 3.5 cm, depending on the study) were 19%, 18%, 18%, and 5%, respectively. The most common complication was pneumothorax, with grade III or higher complications occurring infrequently. The review concluded that microwave ablation is an option for certain patients who are not ideal surgical candidates for the treatment of primary and secondary lung cancers. Estimates of local failure after treatment vary, with more recent studies and smaller tumors associated with higher rates of treatment efficacy.

***Non-Randomized, Retrospective Reviews, and Other Evidence***

Reisenauer et al. (2022) conducted a small prospective clinical trial on percutaneous microwave ablation in patients with primary or metastatic lung cancer < 3cm in size and 1 cm away from the pleura. The trial's main objective was to demonstrate the safety and efficacy of microwave ablation on primary or metastatic lung cancer with a follow up of 1 year post treatment. A total of 6 patients, 7 lesions total with an average size of 10.7 mm (IQR, 6-14), underwent microwave ablation at 75W for an average of 5.9 minutes (IQR, 3-10). Twelve adverse events were reported (1 Grade 3, 3 Grade 2, and 8 Grade 1 events) with Grade 4 or 5 events. At three month follow up the lesions decreased in size, rim thickness, fluorodeoxyglucose activity, and T2 signal. At 6 month follow up fluorodeoxyglucose activity was below blood pool in all case, and by 12 months all ablation zones stabilized. One patient expired during the study from pneumonia unrelated to ablation without local recurrence. Of the seven ablations there was one local tumor recurrence at 271 days following ablation at the apex of the ablation zone, subsequently successfully treated with percutaneous cryoablation.

Wang J et al. (2022) conducted a retrospective data analysis on 48 small lung cell cancer patients who underwent microwave ablation. The median overall survival for all small lung cell cancer was 27.0 months (95% confidence interval 22.4-31.6 months). The overall survival of small lung cell cancer with tumor diameter ≤ 3.0 cm was longer than that of tumor diameter >3.0 cm (median 48.0 months vs. 27.0 months, P = 0.041). For limited stage small lung cell cancer, the 1-, 2-, 3-, and 5-year survival rate was 91.67%, 72.22%, 66.67%, and 61.11%, respectively; while for extensive

stage small lung cell cancer the 1-, 2-, and 3-year survival rates were 83.33%, 50.0%, and 8.33%. Major complications included pneumothorax needing tube placement (29.4%), rarely arrhythmia (2.0%), empyema (2.0%), pulmonary fungal infection (2.0%), and shingles (2.0%). The data supports the guidelines endorsing microwave ablation therapy as a safe and effective therapy for inoperable tumors < 3 cm.

**National and Specialty Organizations**

**National Comprehensive Cancer Network (NCCN)**

Hepatocellular Cancers ([1]NCCN 2024)

- The guidelines (v 3.2024) on hepatocellular carcinoma lists microwave ablation, in addition to radiofrequency ablation, cryoablation and percutaneous alcohol injection, as a treatment option for hepatocellular carcinoma in patients who are not candidates for potential curative treatments (e.g., resection and transplantation) and do not have large-volume extrahepatic disease. Ablation should only be considered for tumors that can be accessed via percutaneous, laparoscopic, or open approaches. For tumors 3 cm or smaller, ablation alone may be curative and, in well-selected cases with properly located tumors, may be a definitive treatment if reviewed by a multidisciplinary team. Lesions between 3 and 5 cm can be treated to prolong survival by combining arterially directed therapies with ablation. Lesions over 5 cm, if unresectable or inoperable, should be considered for treatment through arterially directed therapy.

Small Cell Lung Cancer ([2]NCCN 2024)

- The guidelines do not mention microwave ablation directly.

Non-Small Cell Lung Cancer ([3]NCCN 2024)

- The guidelines on Non-Small Cell Lung Cancer (v 4.2023) mention for medically inoperable disease that image guided stereotactic ablative radiotherapy (e.g., cryotherapy, microwave, radiofrequency) is preferred. The guidelines also mention for multiple lung cancers with dominant nodule with evidence of growth and definitive local therapy is possible that image guided thermal ablation (e.g., cryotherapy, microwave, radiofrequency) is one of three treatment options.

The **National Institute for Health and Care Excellence (NICE)**

Primary or Metastatic Cancer in the Lungs (NICE 2022)

- The guidelines for microwave ablation in treating primary or metastatic lung cancer state that while there is sufficient evidence supporting its safety, there is also a risk of infrequent but serious complications. Evidence shows that the procedure effectively reduces tumor size, but data on its impact on survival rates, long-term outcomes, and quality of life is limited in both scope and quality. It is recommended that this procedure only be performed with special arrangements for clinical oversight, patient consent, and ongoing auditing or research.

Hepatocellular Carcinoma or Liver Metastases (NICE 2016, 2007)

- The guidelines for microwave ablation in treating liver metastases indicate that current evidence does not raise significant safety concerns, and there is adequate data supporting its effectiveness in tumor ablation. This treatment approach can be implemented when standard protocols for clinical governance, patient consent, and auditing are in place. It is recommended that patients be selected by a multidisciplinary hepatobiliary cancer team. Additionally, further research could improve patient selection by examining factors such as the primary tumor's location and type, the intended treatment outcome (whether palliative or curative), imaging methods used to assess the procedure's success, and data on long-term outcomes and survival.

- The guidelines for microwave ablation in treating hepatocellular carcinoma suggest that the available evidence supports the safety and efficacy of microwave ablation as a treatment option, provided that clinical governance, patient consent, and audit protocols are established. While no major concerns have been raised regarding its efficacy, the guidelines note that long-term survival data remains limited, highlighting an area where further research could be valuable.

## CODING & BILLING INFORMATION

**CPT (Current Procedural Terminology)**

| Code | Description |
|---|---|
| **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 |
| **47370** | Laparoscopy, surgical, ablation of 1 or more liver tumor(s); radiofrequency |
| **47380** | Ablation, open, of 1 or more liver tumor(s); radiofrequency |
| **47382** | Ablation, 1 or more liver tumor(s), percutaneous, radiofrequency |
| **47399** | Unlisted procedure, liver |
| **76940** | Ultrasound guidance for, and monitoring of, parenchymal tissue ablation |
| **77013** | Computed tomography guidance for, and monitoring of, parenchymal tissue ablation |

**HCPCS (Healthcare Common Procedure Coding System)**

| Code | Description |
|---|---|
| **C9751** | Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3D rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (e.g., aspiration[s]/biopsy[ies]) and all mediastinal and/or hilar lymph node stations or structures and therapeutic intervention(s) |

**CODING DISCLAIMER.** Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

## APPROVAL HISTORY

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|---|---|
| **12/11/2024** | Policy reviewed No changes to coverage criteria. Updated Summary of Medical Evidence and References. |
| **12/13/2023** | Policy reviewed. No changes to coverage criteria. Title changed to "Microwave Ablation of Lung and Liver Tumors." Updated references and summary of medical evidence. |
| **12/14/2022** | New policy. IRO Peer Review: 12/14/2022 by a practicing physician board-certified in Radiation Oncology. |

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