Microwave Tumor Ablation

**Policy # 00569**

**Original Effective Date:** 10/01/2017

**Current Effective Date:** 05/08/2023

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Cryoablation of Tumors Located in the Kidney, Lung, Breast, Pancreas, or Bone is addressed separately in medical policy 00023.

Note: Radioembolization for Primary and Metastatic Tumors of the Liver is addressed separately in medical policy 00110.

Note: Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors is addressed separately in medical policy 00175.

Note: Radiofrequency Ablation of Primary or Metastatic Liver Tumors is addressed separately in medical policy 00182.

Note: Cryosurgical Ablation of Primary or Metastatic Liver Tumors is addressed separately in medical policy 00220.

Note: Transcatheter Arterial Chemoembolization (TACE) to Treat Primary or Metastatic Liver Malignancies is addressed separately in medical policy 00227.

**When Services May Be Eligible for Coverage**

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member’s contract/certificate, and
- Medical necessity criteria and guidelines are met.

**Hepatic Tumors**

Based on review of available data, the Company may consider microwave ablation of primary or metastatic hepatic tumors to be eligible for coverage.**
Microwave Tumor Ablation

Policy #  00569
Original Effective Date:  10/01/2017
Current Effective Date:  05/08/2023

Patient Selection Criteria
Coverage eligibility for microwave ablation of primary or metastatic hepatic tumors will be considered when ALL criteria are met:
- The tumor is unresectable due to location of lesion[s] and/or comorbid conditions AND
- A single tumor of ≤5 cm or up to 3 nodules ≤3 cm each.

Lung Tumors
Based on review of available data, the Company may consider microwave ablation of primary or metastatic lung tumors to be eligible for coverage.**

Patient Selection Criteria
Coverage eligibility for microwave ablation of primary or metastatic lung tumors will be considered when ALL criteria are met:
- The tumor is unresectable due to location of lesion[s] and/or comorbid conditions; AND
- A single tumor of ≤3 cm.

When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers microwave ablation of primary or metastatic tumors other than liver or lung to be investigational.*

Based on review of available data, the Company considers microwave ablation of more than a single primary or metastatic tumor in the lung to be investigational.*

The use of microwave ablation when patient selection criteria are not met is considered to be investigational.*

Background/Overview
Microwave Ablation
Microwave ablation (MWA) uses microwave energy to induce an ultra-high-speed, 915 MHz or 2,450 MHz (2.45 GHz), alternating electric field, which causes water molecule rotation and creates
Microwave Tumor Ablation

Policy # 00569
Original Effective Date: 10/01/2017
Current Effective Date: 05/08/2023

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, 2 to 3 cm elliptical area 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 the 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 tumor size. The cells killed by MWA are typically not removed but are gradually replaced by fibrosis and scar tissue. If there is a local recurrence, it occurs at the margins. Treatment may be repeated as needed. Microwave ablation may be used for the following purposes: (1) to control local tumor growth and prevent recurrence; (2) to palliate symptoms; and (3) to prolong survival.

Microwave ablation is similar to radiofrequency (RFA) and cryosurgical ablation. However, MWA has potential advantages over RFA and cryosurgical ablation. In MWA, the heating process is active, which produces higher temperatures than the passive heating of RFA and should allow for more complete thermal ablation in less time. The higher temperatures reached with MWA (>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. Microwave ablation does not rely on the conduction of electricity for heating and, therefore, does not flow electrical current through patients and does not require grounding pads, because there is no risk of skin burns. Additionally, MWA does not produce electric noise, which allows ultrasound guidance during the procedure without interference, unlike RFA. Finally, MWA can take 20% to 30% less time than RFA, because multiple antennas can be used simultaneously for multiple ablations. There is no comparable RFA system with the capacity to drive multiple electrically dependent electrodes.

Adverse Events
Complications from MWA may include pain and fever. Other complications associated with MWA include those caused by heat damage to normal tissue adjacent to the tumor (eg, intestinal damage during MWA of the kidney or liver), structural damage along the probe track (eg, 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. Microwave ablation should be avoided in pregnant women because potential risks to the patient and/or fetus...
Microwave Tumor Ablation

Policy # 00569
Original Effective Date: 10/01/2017
Current Effective Date: 05/08/2023

have not been established, and in patients with implanted electronic devices (eg, implantable pacemakers) that may be adversely affected by microwave power output.

Applications
Microwave ablation 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). Microwave ablation also has been investigated as a treatment for unresectable hepatic tumors, as both primary and palliative treatment, and as a bridge to a 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.

FDA or Other Governmental Regulatory Approval
U.S. Food and Drug Administration (FDA)
Multiple MWA devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. These devices are indicated for soft tissue ablation, including partial or complete ablation of nonresectable liver tumors. Some devices are specifically cleared for use in open surgical ablation, percutaneous ablation, or laparoscopic procedures. Table 1 is a summary of selected MWA devices cleared by the FDA.

The FDA used determinations of substantial equivalence to existing radiofrequency and MWA devices to clear these devices. FDA product code: NEY.

This medical policy does not address MWA for the treatment of splenomegaly or ulcers, for cardiac applications, or as a surgical coagulation tool.
Microwave Tumor Ablation

Policy #  00569
Original Effective Date:  10/01/2017
Current Effective Date:  05/08/2023

Table 1. Selected Microwave Ablation Devices Cleared by FDA

<table>
<thead>
<tr>
<th>Device</th>
<th>Indication</th>
<th>Manufacturer</th>
<th>Date Cleared</th>
<th>510(k) No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>MedWaves Microwave Coagulation/Ablation System</td>
<td>General surgery use in open procedures for the coagulation and ablation of soft tissues</td>
<td>MedWaves Incorporated</td>
<td>12/2007</td>
<td>K070356</td>
</tr>
<tr>
<td>Acculis Accu2i pMTA Microwave Tissue Ablation Applicator Acculis Accu2i pMTA Applicator and SulisVpMTA Generator</td>
<td>Intraoperative coagulation of soft tissue Software addition</td>
<td>Microsoulis Holdings, Ltd</td>
<td>8/2010 11/2012</td>
<td>K094021 K122762</td>
</tr>
<tr>
<td>MicroThermX Microwave Ablation System</td>
<td>Coagulation (ablation) of soft tissue; may be used in open surgical as well as percutaneous ablation procedures</td>
<td>BSD Medical Corporation</td>
<td>8/2010</td>
<td>K100786</td>
</tr>
<tr>
<td>Emprint™‡ Ablation System Emprint™‡ Ablation System Emprint™‡ SX Ablation Platform with Thermosphere™‡ Technology Emprint™‡ Ablation Platform with Thermosphere™‡</td>
<td>Percutaneous, laparoscopic, and intraoperative coagulation (ablation) of soft tissue, including partial or complete ablation of non-resectable liver tumors Same with design modification of device antenna for percutaneous use 3-D navigation feature</td>
<td>Medtronic</td>
<td>4/2014 12/2016 9/2017 2/2020</td>
<td>K133821 K163105 K171358 K193232</td>
</tr>
</tbody>
</table>
Microwave Tumor Ablation

Policy # 00569
Original Effective Date: 10/01/2017
Current Effective Date: 05/08/2023

<table>
<thead>
<tr>
<th>Technology and Emprint™ SX Ablation Platform with Thermosphere™ Technology</th>
<th>assists in the placement of antenna using real-time image guidance during intraoperative and laparoscopic ablation procedures</th>
<th>Antenna modification and update to instructions for use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Certus 140 2.45 GHz Ablation System and Accessories</td>
<td>Ablation (coagulation) of soft tissue</td>
<td>Certus 140™‡ 2.45 GHz Ablation System and Accessories</td>
</tr>
<tr>
<td>CertuSurg™‡ Surgical Tool</td>
<td>Ablation (coagulation) of soft tissue in percutaneous, open surgical and in conjunction with laparoscopic surgical settings</td>
<td>Certus 140™‡ 2.45 GHz Ablation System and Accessories</td>
</tr>
<tr>
<td>Certus 140 2.45GHz Ablation System</td>
<td>Surgical coagulation (including Planar Coagulation) in open surgical settings</td>
<td>Certus 140 2.45GHz Ablation System</td>
</tr>
<tr>
<td></td>
<td>Same indication with probe redesign</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ablation (coagulation) of soft tissue in percutaneous, open surgical and in conjunction with</td>
<td></td>
</tr>
</tbody>
</table>

Johnson & Johnson 10/2010 01/2012 07/2013 05/2016 10/2018 K100744 K113237 K130399 K160936 K173756
Microwave Tumor Ablation

Policy # 00569
Original Effective Date: 10/01/2017
Current Effective Date: 05/08/2023

<table>
<thead>
<tr>
<th>System</th>
<th>Procedure Details</th>
<th>Manufacturer</th>
<th>Date</th>
<th>FDA Approval Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>NEUWAVE Flex Microwave Ablation System (FLEX)</td>
<td>Ablation (coagulation) of soft tissue; design evolution of Certus 140 2.45GHz Ablation System (K160936)</td>
<td>Johnson &amp; Johnson</td>
<td>3/2017</td>
<td>K163118</td>
</tr>
<tr>
<td>Solero Microwave Tissue Ablation (MTA) System and Accessories</td>
<td>Ablation of soft tissue during open procedures</td>
<td>Angiodynamics, Inc.</td>
<td>5/2017</td>
<td>K162449</td>
</tr>
<tr>
<td>Microwave Ablation System</td>
<td>Coagulation (ablation) of soft tissue</td>
<td>Surgnova Healthcare Technologies (Zhejiang) Co., Ltd</td>
<td>7/2019</td>
<td>K183153</td>
</tr>
<tr>
<td>NEUWAVE Microwave Ablation System and Accessories</td>
<td>Ablation (coagulation) of soft tissue in percutaneous, open surgical and in conjunction with laparoscopic surgical settings, including the partial or complete ablation of non-resectable liver tumors; not intended for use in cardiac procedures</td>
<td>Johnson &amp; Johnson</td>
<td>11/2020</td>
<td>K200081</td>
</tr>
</tbody>
</table>

FDA: U.S. Food and Drug Administration.

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.

Page 7 of 28
Microwave Tumor Ablation

Policy # 00569
Original Effective Date: 10/01/2017
Current Effective Date: 05/08/2023

**Rationale/Source**
This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Microwave ablation (MWA) is a technique to destroy tumors and soft tissue using microwave energy to create thermal coagulation and localized tissue necrosis. Microwave ablation is used to treat tumors not amenable to resection and to treat patients ineligible for surgery due to age, comorbidities, or poor general health. Microwave ablation may be performed as an open procedure, laparoscopically, percutaneously, or thoracoscopically under image guidance (eg, ultrasound, computed tomography, magnetic resonance imaging) with sedation, or local or general anesthesia. This technique is also referred to as microwave coagulation therapy.

**Summary of Evidence**
For individuals who have an unresectable primary or metastatic hepatic tumor who receive MWA, the evidence includes randomized controlled trials (RCTs), comparative observational studies, and systematic reviews comparing MWA to radiofrequency ablation (RFA) and to surgical resection. Relevant outcomes are overall survival (OS), disease-specific survival, symptoms, quality of life (QOL), and treatment-related mortality and morbidity. The body of evidence indicates that MWA is an effective option in patients for whom resection is not an option. Although studies had methodological limitations, results consistently showed that MWA and RFA had similar survival outcomes with up to 5 years of follow-up in patients with a single tumor ≤5 cm or up to 3 nodules ≤3 cm each. In a meta-analysis of observational studies, patients receiving MWA had higher local recurrence rates and lower survival than those who received resection, but the patient populations were not limited to those who had unresectable tumors. Microwave ablation was associated with lower complications, intraoperative blood loss, and hospital length of stay. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have an unresectable primary or metastatic lung tumor who receive MWA, the evidence includes a single RCT, retrospective observational studies, and systematic reviews of these
Microwave Tumor Ablation

Policy # 00569
Original Effective Date: 10/01/2017
Current Effective Date: 05/08/2023

studies. Relevant outcomes are OS, disease-specific survival, symptoms, QOL, and treatment-related mortality and morbidity. The body of evidence indicates that MWA is an effective option in patients for whom resection is not an option. In the RCT, direct comparison of MWA and RFA in patients with primary or metastatic lung cancer (mean tumor size, 1.90 cm [± 0.89] at baseline) found similar mortality rates up to 12 months of follow-up. In the first of 3 systematic reviews that included 12 retrospective observational studies, local recurrence rates were similar for MWA and RFA at a range of 9 to 47 months of follow-up. In the second systematic review with a meta-analysis, there was lower OS with MWA compared to RFA but studies were not directly comparable due to clinical and methodological heterogeneity. However, the authors concluded that percutaneous RFA and MWA were both effective with a high safety profile. In the third systematic review using a network meta-analysis, the weighted average OS rates for MWA were 82.5%, 54.6%, 35.7%, 29.6%, and 16.6% at 1, 2, 3, 4, and 5 years, respectively. Limitations of the body of evidence included a lack of controlled studies and heterogeneity across studies. The RCT did not report results by tumor size or the number of metastases. The observational studies included in the systematic reviews did not report sufficient information to assess the effectiveness or safety of MWA in subgroups based on the presence of multiple tumors or total tumor burden. Therefore, conclusions about the evidence sufficiency can only be made about patients with single tumors. For this population, the evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have an unresectable primary or metastatic renal tumor who receive MWA, the evidence includes a single RCT that compared MWA to partial nephrectomy, retrospective reviews, systematic reviews, and meta-analyses of the retrospective reviews (with or without the single RCT) and case series. Relevant outcomes are OS, disease-specific survival, symptoms, QOL, and treatment-related mortality and morbidity. In the RCT, overall local recurrence-free survival at 3 years was 91.3% for MWA and 96.0% for partial nephrectomy (p=.54). This positive outcome should be replicated in additional RCTs. There are also no controlled studies comparing MWA to other ablation techniques in patients with renal tumors. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have unresectable primary or metastatic solid tumors other than hepatic, lung, or renal who receive MWA, the evidence includes systematic reviews and case series. Relevant outcomes are OS, disease-specific survival, symptoms, QOL, and treatment-related mortality and morbidity. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.
Microwave Tumor Ablation

Policy # 00569  
Original Effective Date: 10/01/2017  
Current Effective Date: 05/08/2023

**Supplemental Information**

**Clinical Input From Physician Specialty Societies and Academic Medical Centers**

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

**2016 Input**

In response to requests, input was received from 2 physician specialty societies and 1 academic medical center while this policy was under review in 2016. This number of responses was less than optimal. Input overall was mixed. There was some support for the medical necessity of microwave ablation (MWA) in each category, with some reviewers indicating that it was standard of care for certain tumors. However, there were no indications for which all 3 reviewers agreed that MWA should be medically necessary.

**2011 Input**

In response to requests, input was received from 2 physician specialty societies (3 reviews) and 4 academic medical centers (6 reviews) while this policy was in development. Eight reviewers considered MWA investigational to treat primary tumors such as hepatocellular carcinoma, benign and malignant renal tumors, lung tumors, adrenal tumors, or cholangiocarcinoma. The reviewers noted insufficient evidence and a need for further studies on MWA. However, 1 reviewer indicated MWA for primary tumors, including, but not limited to hepatocellular carcinoma, benign and malignant renal tumors, lung tumors, adrenal tumors, and cholangiocarcinoma, may be considered a treatment option, and another reviewer indicated that MWA for renal tumors may be considered a treatment option.

Four reviewers considered MWA investigational to treat liver metastases, and 2 reviewers indicated MWA for liver metastases may be considered a treatment option. One reviewer noted MWA may be appropriate for tumors not amenable to radiofrequency ablation or other local treatments. This reviewer also suggested MWA may be more appropriate for tumors located near large blood vessels.
Microwave Tumor Ablation

Policy # 00569
Original Effective Date: 10/01/2017
Current Effective Date: 05/08/2023

Practice Guidelines and Position Statements
Guidelines or position statements will be considered for inclusion in ‘Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

National Comprehensive Cancer Network
The National Comprehensive Cancer Network (NCCN) guidelines on hepatobiliary cancers (v.2.2022 ) list MWA (along with radiofrequency ablation, cryoablation, and percutaneous alcohol injection) as a treatment option for hepatocellular carcinoma (HCC) tumors in patients who are not candidates for potential curative treatments (eg, resection and transplantation) and do not have large-volume extrahepatic disease. Ablation should only be considered when tumors are accessible by percutaneous, laparoscopic, or open approaches. The guidelines indicate "Ablation alone may be curative in treating tumors less than or equal to 3 cm [...] Lesions 3 to 5 cm may be treated to prolong survival using arterially directed therapies, or with combination of an arterially directed therapy and ablation as long as tumor location is accessible for ablation."

The guidelines on non-small cell lung cancer (NSCLC) (v.3.2022 ) state that image-guided thermal ablation therapies such as cryotherapy, microwave, or radiofrequency may be an option for select medically inoperable patients not receiving stereotactic ablative radiotherapy or definitive radiotherapy. Image-guided thermal ablation therapy is considered an option for the management of NSCLC lesions <3 cm. Ablation for NSCLC lesions >3 cm has been associated with higher rates of local recurrence and complications.

Guidelines on small-cell lung cancer (v. 1.2023 ) state, "stereotactic ablative radiotherapy is an option for certain patients with medically inoperable stage I to IIA small-cell lung cancer."

The Network guidelines on neuroendocrine tumors (v.1.2022 ) state that cytoreductive surgery or ablative therapies (eg, radiofrequency, cryotherapy, microwave) may be considered in patients with progressive hepatic-predominant metastatic disease to reduce tumor bulk and relieve symptoms of hormone hypersecretion (category 2B). Additionally, although prospective data for ablative therapy interventions are limited, the guideline notes that "percutaneous thermal ablation, often using
Microwave Tumor Ablation

Policy #  00569
Original Effective Date:  10/01/2017
Current Effective Date:  05/08/2023

Microwave energy, can be considered for oligometastatic liver disease, generally up to 4 lesions each smaller than 3 cm.

The guidelines on kidney cancer (v.2.2023 ) do not specifically address the role of MWA, but state that other thermal ablation techniques (RFA and cryotherapy) may be an option for T1 renal lesions, particularly for masses <3 cm.

The guidelines on breast cancer (v 4.2022. ) do not address thermal ablation techniques such as MWA.

**National Institute for Health and Care Excellence**
The National Institute for Health and Care Excellence (2016) updated its guidance on MWA for treatment of metastases in the liver. The revised guidance states:

- Current evidence on MWA for treating liver metastases raises no major safety concerns and the evidence on efficacy is adequate in terms of tumor ablation. Therefore this procedure may be used provided that standard arrangements are in place for clinical governance, consent, and audit.
- Patient selection should be carried out by a hepatobiliary cancer multidisciplinary team.
- Further research would be useful for guiding the selection of patients for this procedure. This should document the site and type of the primary tumor being treated, the intention of treatment (palliative or curative), imaging techniques used to assess the efficacy of the procedure, long-term outcomes, and survival.

The Institute (2007) also published guidance on MWA for HCC. This guidance indicated: “Current evidence on the safety and efficacy of MWA of hepatocellular carcinoma appears adequate to support the use of this procedure….” The guidance also stated there are no major concerns about the efficacy of MWA, but noted that limited, long-term survival data are available.

The Institute (2013) has published guidance on MWA for lung tumors as well. This guidance indicated that “evidence that the procedure improves clinical outcomes and quality of life is limited in quantity and quality. There is a risk of complications, including pneumothorax, which may have serious implications for patients with already compromised lung function. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit.” The guidance encourages further research.

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.
Microwave Tumor Ablation

Policy # 00569
Original Effective Date: 10/01/2017
Current Effective Date: 05/08/2023

American College of Chest Physicians
The American College of Chest Physicians (2013) evidence-based guidelines on the treatment of NSCLC noted that the role of ablative therapies in the treatment of high-risk patients with stage I NSCLC is evolving. The guidelines deal mostly with radiofrequency ablation.

American Urological Association
The American Urological Association (2021) updated its guidelines on renal mass and localized renal cancer, which note that both RFA and cryoablation may be offered as options for patients who elect thermal ablation (Conditional Recommendation; Evidence Level: Grade C). Thermal ablation can be considered as an alternate approach in the management of T1a solid renal masses <3 cm. In these patients, a percutaneous technique is preferred (Moderate Recommendation; Evidence Level: Grade C). The guidelines do not specifically address MWA.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some currently ongoing and unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT04197960</td>
<td>A Prospective Multicenter Study to Compare the Therapeutic Outcomes of Microwave Ablation with Surgical Resection for Micropapillary Thyroid Carcinoma</td>
<td>973</td>
<td>Dec 2022</td>
</tr>
</tbody>
</table>
Microwave Tumor Ablation

Policy # 00569
Original Effective Date: 10/01/2017
Current Effective Date: 05/08/2023

<table>
<thead>
<tr>
<th>NCT Number</th>
<th>Study Description</th>
<th>Study Number</th>
<th>Study End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCT04626986</td>
<td>Comparison of Ultrasound Guided Percutaneous Microwave Ablation With Breast Conserving Surgery for Breast Tumor</td>
<td>300</td>
<td>May 2023</td>
</tr>
<tr>
<td>NCT04081168</td>
<td>COLLISION XL: Unresectable Colorectal Liver Metastases (3-5cm): Stereotactic Body Radiotherapy vs. Microwave Ablation (COLLISION-XL)</td>
<td>68</td>
<td>Jan 2025</td>
</tr>
<tr>
<td>NCT03775980</td>
<td>CIRSE Emprint Microwave Ablation Registry (CIEMAR)</td>
<td>1000</td>
<td>Jul 2026</td>
</tr>
<tr>
<td>NCT04365751</td>
<td>To Compare the Efficacy of Microwave Ablation and Laparoscopic Hepatectomy for Hepatocellular Carcinoma</td>
<td>1134</td>
<td>Dec 2026</td>
</tr>
<tr>
<td>NCT04107766</td>
<td>NeuWave Observational Liver Ablation Registry (NOLA)</td>
<td>1500</td>
<td>Dec 2027</td>
</tr>
<tr>
<td>NCT02642185</td>
<td>Microwave Ablation Versus Resection for Resectable Colorectal Liver Metastases (MAVERRIC)</td>
<td>102</td>
<td>Jan 2022</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.
a Denotes industry-sponsored or cosponsored trial.

References

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.
Microwave Tumor Ablation

Policy # 00569
Original Effective Date: 10/01/2017
Current Effective Date: 05/08/2023


Microwave Tumor Ablation

Policy # 00569
Original Effective Date: 10/01/2017
Current Effective Date: 05/08/2023


Microwave Tumor Ablation

Policy # 00569
Original Effective Date: 10/01/2017
Current Effective Date: 05/08/2023

Microwave Tumor Ablation

Policy # 00569
Original Effective Date: 10/01/2017
Current Effective Date: 05/08/2023


Microwave Tumor Ablation

Policy #  00569
Original Effective Date:  10/01/2017
Current Effective Date:  05/08/2023


Microwave Tumor Ablation

Policy # 00569
Original Effective Date: 10/01/2017
Current Effective Date: 05/08/2023


©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.
Microwave Tumor Ablation

Policy # 00569
Original Effective Date: 10/01/2017
Current Effective Date: 05/08/2023

86. Vogl TJ, Eckert R, Naguib NN, et al. Thermal Ablation of Colorectal Lung Metastases: Retrospective Comparison Among Laser-Induced Thermotherapy, Radiofrequency Ablation,
Microwave Tumor Ablation

Policy # 00569
Original Effective Date: 10/01/2017
Current Effective Date: 05/08/2023

and Microwave Ablation. AJR Am J Roentgenol. Dec 2016; 207(6): 1340-1349. PMID 27680945

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.
Microwave Tumor Ablation

Policy #  00569
Original Effective Date:  10/01/2017
Current Effective Date:  05/08/2023

Microwave Tumor Ablation

Policy # 00569
Original Effective Date: 10/01/2017
Current Effective Date: 05/08/2023


Microwave Tumor Ablation

Policy # 00569
Original Effective Date: 10/01/2017
Current Effective Date: 05/08/2023


Policy History
Original Effective Date: 10/01/2017
Current Effective Date: 05/08/2023
07/06/2017 Medical Policy Committee review
07/19/2017 Medical Policy Implementation Committee approval. New policy.
01/01/2018 Coding update
07/05/2018 Medical Policy Committee review
07/03/2019 Medical Policy Committee review
11/07/2019 Medical Policy Committee review
11/13/2019 Medical Policy Implementation Committee approval. Coverage changes from investigational position only to may be eligible for hepatic and lung tumors with specific criteria. For Hepatic tumors conditions for may be eligible for coverage include: the tumor is unresectable due to location of lesion[s] and/or comorbid conditions and a single tumor of ≤5 cm or up to 3 nodules <3 cm each. For Lung tumors conditions include: the tumor is unresectable due to location of lesion and/or comorbid conditions and a single tumor of ≤3 cm.
04/02/2020 Medical Policy Committee review
04/08/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/01/2021 Medical Policy Committee review
04/14/2021 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/07/2022 Medical Policy Committee review
Microwave Tumor Ablation

Policy # 00569
Original Effective Date: 10/01/2017
Current Effective Date: 05/08/2023

04/13/2022 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/06/2023 Medical Policy Committee review
04/12/2023 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date: 04/2024

Coding
The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®), copyright 2022 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.
Microwave Tumor Ablation

Policy #  00569  
Original Effective Date:  10/01/2017  
Current Effective Date:  05/08/2023

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

<table>
<thead>
<tr>
<th>Code Type</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td>19499, 32998, 47382, 50592, 76940, 77499</td>
</tr>
<tr>
<td>HCPCS</td>
<td>C9751</td>
</tr>
<tr>
<td>ICD-10 Diagnosis</td>
<td>All related diagnoses</td>
</tr>
</tbody>
</table>

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
Microwave Tumor Ablation

Policy #  00569
Original Effective Date:  10/01/2017
Current Effective Date:  05/08/2023

C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.