Blue Cross Blue Shield of Rhode Island

EFFECTIVE DATE: 02|01|2020
POLICY LAST UPDATED: 10|01|2020

OVERVIEW

Microwave ablation (MWA) is a technique to destroy tumors and soft tissue using microwave energy to create thermal coagulation and localized tissue necrosis. MWA is used to treat tumors not amenable to resection and to treat patients ineligible for surgery due to age, comorbidities, or poor general health. MWA 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.

MEDICAL CRITERIA

Microwave ablation of primary or metastatic hepatic tumors may be considered covered under the following conditions:

- The tumor is unresectable due to location of lesion[s] and/or comorbid conditions
- A single tumor of ≤5 cm or up to 3 nodules ≤3 cm each

Microwave ablation of primary or metastatic lung tumors may be considered covered under the following conditions:

- The tumor is unresectable due to location of lesion and/or comorbid conditions
- A single tumor of ≤3 cm

PRIOR AUTHORIZATION

Prior authorization is required for BlueCHiP for Medicare members and recommended for Commercial products.

POLICY STATEMENT

BlueCHiP for Medicare and Commercial Products

Microwave ablation is considered medically necessary when the medical criteria above have been met.

Microwave ablation of more than a single primary or metastatic tumor in the lung is considered not covered for BlueCHiP for Medicare and not medically necessary for Commercial as the evidence is insufficient to determine the effects of the technology on health outcomes.

Microwave ablation of primary or metastatic tumors other than liver or lung is considered not covered for BlueCHiP for Medicare and not medically necessary for Commercial as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate section of the Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable surgery benefits/coverage.

BACKGROUND

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 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 cm to 3cm elliptical area (5´3 cm) of tissue ablation. In tumors greater than 2 cm in diameter, two to three 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 one 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. MWA 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.

MWA 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. MWA 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 less time than RFA, because multiple antennas can be used simultaneously.

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. MWA should be avoided in pregnant women because potential risks to the patient and/or fetus have not been established, and in patients with implanted electronic devices (eg, implantable pacemakers) that may be adversely affected by microwave power output.

Applications

MWA was first used percutaneously in 1986 as an adjunct to liver biopsy. Since then, MWA has been used to ablate tumors and tissue to treat many conditions including hepatocellular carcinoma, breast cancer, colorectal cancer metastatic to the liver, renal cell carcinoma, renal hamartoma, adrenal malignant carcinoma, non-small-cell lung cancer, intrahepatic primary cholangiocarcinoma, secondary splenomegaly and hypersplenism, abdominal tumors, and other tumors not amenable to resection. Well-established local or systemic treatment alternatives are available for each of these malignancies. The potential advantages of MWA for these cancers include improved local control and other advantages common to any minimally invasive procedure (eg, preserving normal organ tissue, decreasing morbidity, shortening length of hospitalization). MWA also has been investigated as a treatment for unresectable hepatic tumors, as both primary and palliative treatment, and as a bridge to 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.

Regulatory Status

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.

For individuals who have unresectable primary or metastatic breast cancer who receive MWA, the evidence includes case series and a systematic review of feasibility and pilot studies conducted prior to 2010. Relevant outcomes are OS, disease-specific survival, symptoms, quality of life, and treatment-related mortality and morbidity. The evidence is insufficient to determine the effects of the technology on health outcomes.

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 RFA and to surgical resection. The 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, they consistently showed that MWA and RFA had similar survival outcomes with up to five years of follow-up in patients with a single tumor <5 cm or up to three 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. MWA was associated with lower complications, intraoperative blood loss, and hospital length of stay. The evidence is sufficient to determine the effects of the technology on health outcomes.

For individuals who have an unresectable primary or metastatic lung tumor who receive MWA, the evidence includes one RCT, retrospective observational studies, and systematic reviews of these studies. The 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 the effects of the technology on health outcomes.

For individuals who have an unresectable primary or metastatic renal tumor who receive MWA, the evidence includes one RCT that compared MWA to partial nephrectomy retrospective reviews, and case series. The 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=0.54). 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 the effects of the technology on health outcomes.

For individuals who have unresectable primary or metastatic solid tumors other than breast, hepatic, lung, or renal who receive MWA, the evidence includes systematic reviews and case series. Relevant outcomes are OS, disease-specific survival, symptoms, quality of life, and treatment-related mortality and morbidity. The evidence is insufficient to determine the effects of the technology on health outcomes.

CODING

BlueCHiP for Medicare and Commercial Products

There are no CPT codes specific to microwave tumor ablation. Report the unlisted CPT code for the anatomic area.

The following related HCPCS code is covered if the medical criteria are met:

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)

RELATED POLICIES

Unlisted Procedures

PUBLISHED

Provider Update, December 2020
Provider Update, February 2020
Provider Update, August 2018
Provider Update, June 2017
Provider Update, May 2016
Provider Update, May 2015
Provider Update, June 2014
Provider Update, November 2013

REFERENCES

1. Zhao Z, Wu F. Minimally-invasive thermal ablation of early-stage breast cancer: a systematic review. Eur J Surg Oncol. Dec 2010;36(12):1149-1155. PMID 20889281.
2. Zhou W, Zha X, Liu X, et al. US-guided percutaneous microwave coagulation of small breast cancers: a clinical study. Radiology. May 2012;263(2):364-373. PMID 22438362.
3. Chinnaratha MA, Chuang MY, Fraser RJ, et al. Percutaneous thermal ablation for primary hepatocellular carcinoma: A systematic review and meta-analysis. J Gastroenterol Hepatol. Feb 2016;31(2):294-301. PMID 26114968.
4. Bertot LC, Sato M, Tateishi R, et al. Mortality and complication rates of percutaneous ablative techniques for the treatment of liver tumors: a systematic review. Eur Radiol. Dec 2011;21(12):2584-2596. PMID 21858539.
5. Ong SL, Gravante G, Metcalfe MS, et al. Efficacy and safety of microwave ablation for primary and secondary liver malignancies: a systematic review. Eur J Gastroenterol Hepatol. Jun 2009;21(6):599-605. PMID 19282763.
6. Glassberg MB, Ghosh S, Clymer JW et al. Microwave ablation compared with hepatic resection for the treatment of hepatocellular carcinoma and liver metastases: a systematic review and meta-analysis. World J Surg Oncol, 2019 Jun 12;17(1). PMID 31182102.
7. Shibata T, Iimuro Y, Yamamoto Y, et al. Small hepatocellular carcinoma: comparison of radio-frequency ablation and percutaneous microwave coagulation therapy. Radiology. May 2002;223(2):331-337. PMID 11997534.
8. Xu J, Zhao Y. Comparison of percutaneous microwave ablation and laparoscopic resection in the prognosis of liver cancer. Int J Clin Exp Pathol, 2015 Dec 1;8(9). PMID 26617907.
9. Vietti Violi N, Duran R, Guiu B et al. Efficacy of microwave ablation versus radiofrequency ablation for the treatment of hepatocellular carcinoma in patients with chronic liver disease: a randomised controlled phase 2 trial. Lancet Gastroenterol Hepatol, 2018 Mar 6;3(5). PMID 29503247.

10. Shibata T, Iimuro Y, Yamamoto Y et al. Small hepatocellular carcinoma: comparison of radio-frequency ablation and percutaneous microwave coagulation therapy. Radiology, 2002 May 9;223(2). PMID 11997534.
11. Yu J, Yu XL, Han ZY et al. Percutaneous cooled-probe microwave versus radiofrequency ablation in early-stage hepatocellular carcinoma: a phase III randomised controlled trial. Gut, 2016 Nov 26;66(6). PMID 27884919.
12. Yu J, Liang P, Yu XL, et al. Needle track seeding after percutaneous microwave ablation of malignant liver tumors under ultrasound guidance: analysis of 14-year experience with 1462 patients at a single center. Eur J Radiol. Oct 2012;81(10):2495-2499. PMID 22137097.
13. Zhou P, Liang P, Dong B, et al. Long-term results of a phase II clinical trial of superantigen therapy with staphylococcal enterotoxin C after microwave ablation in hepatocellular carcinoma. Int J Hyperthermia. Dec 2011;27(2):132-139. PMID 21117923.
14. Zhou P, Liang P, Yu X, et al. Percutaneous microwave ablation of liver cancer adjacent to the gastrointestinal tract. J Gastrointest Surg. Feb 2009;13(2):318-324. PMID 18825464.
15. Lu MD, Xu HX, Xie XY, et al. Percutaneous microwave and radiofrequency ablation for hepatocellular carcinoma: a retrospective comparative study. J Gastroenterol. Nov 2005;40(11):1054-1060. PMID 16322950.
16. Tanaka K, Shimada H, Nagano Y, et al. Outcome after hepatic resection versus combined resection and microwave ablation for multiple bilobar colorectal metastases to the liver. Surgery. Feb 2006; 139(2): 263-73. PMID 16455336
17. Wang ZL, Liang P, Dong BW, et al. Prognostic factors and recurrence of small hepatocellular carcinoma after hepatic resection or microwave ablation: a retrospective study. J Gastrointest Surg. Feb 2008; 12(2): 327-37. PMID 17943391
18. Ohmoto K, Yoshioka N, Tomiyama Y, et al. Comparison of therapeutic effects between radiofrequency ablation and percutaneous microwave coagulation therapy for small hepatocellular carcinomas. J Gastroenterol Hepatol. Feb 2009; 24(2): 223-7. PMID 18823439
19. Yin XY, Xie XY, Lu MD, et al. Percutaneous thermal ablation of medium and large hepatocellular carcinoma: long-term outcome and prognostic factors. Cancer. May 01 2009; 115(9): 1914-23. PMID 19241423
20. Kuang M, Xie XY, Huang C, et al. Long-term outcome of percutaneous ablation in very early-stage hepatocellular carcinoma. J Gastrointest Surg. Dec 2011; 15(12): 2165-71. PMID 21972056
21. Imura S, Shimada M, Utsunomiya T, et al. Ultrasound-guided microwave coagulation assists anatomical hepatic resection. Surg Today. Jan 2012; 42(1): 35-40. PMID 22075665
22. Qian GJ, Wang N, Shen Q, et al. Efficacy of microwave versus radiofrequency ablation for treatment of small hepatocellular carcinoma: experimental and clinical studies. Eur Radiol. Sep 2012; 22(9): 1983-90. PMID 22544225
23. Chinnaratha MA, Sathananthan D, Pateria P, Tse E, MacQuillan G, Wigg AJ. Predictors of hepatocellular carcinoma recurrence post thermal ablation. J Gastroenterol Hepatol. 2013;28(Suppl. 2):66-67.
24. Stattner S, Jones RP, Yip VS, et al. Microwave ablation with or without resection for colorectal liver metastases. Eur J Surg Oncol. Aug 2013; 39(8): 844-9. PMID 23769976
25. Zhang L, Wang N, Shen Q, et al. Therapeutic efficacy of percutaneous radiofrequency ablation versus microwave ablation for hepatocellular carcinoma. PLoS ONE. 2013; 8(10): e76119. PMID 24146824
26. Egorov AV, Vasilyev IA, Musayev GH, et al. The role of microwave ablation in management of functioning pancreatic neuroendocrine tumors. Gland Surg. Dec 2019; 8(6): 766-772. PMID 32042685
27. Guo J, Arellano RS. Percutaneous Microwave Ablation of Stage T1a Renal Cell Carcinoma: Intermediate Results on Safety, Technical Feasibility and Clinical Outcomes of 119 Tumors. AJR Am J Roentgenol. Jun 29 2020. PMID 32603227
28. Aarts BM, Prevoo W, Meier MAJ, et al. Percutaneous Microwave Ablation of Histologically Proven T1 Renal Cell Carcinoma. Cardiovasc Intervent Radiol. Jul 2020; 43(7): 1025-1033. PMID 32052093
29. Egashira Y, Singh S, Bandula S, et al. Percutaneous High-Energy Microwave Ablation for the Treatment of Pulmonary Tumors: A Retrospective Single-Center Experience. J Vasc Interv Radiol. Apr 2016; 27(4): 474-9. PMID 26944360
30. Ko WC, Lee YF, Chen YC, et al. CT-guided percutaneous microwave ablation of pulmonary malignant tumors. J Thorac Dis. Oct 2016; 8(Suppl 9): S659-S665. PMID 28066666

CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS

This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member's subscriber agreement or member certificate and/or the employer agreement, and those documents will supersede the provisions of this medical policy. For information on member-specific benefits, call the provider call center. If you provide services to a member which are determined to not be medically necessary (or in some cases medically necessary services which are non-covered benefits), you may not charge the member for the services unless you have informed the member and they have agreed in writing in advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice. Blue Cross & Blue Shield of Rhode Island is an independent licensee of the Blue Cross and Blue Shield Association.