

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

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 (RFA), cryoablation, microwave ablation, and laser ablation. **Microwave ablation (MWA)**, 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 (Putzer et al. 2020). MWA is an ablative procedure similar to radiofrequency or cryosurgical ablation; however, in MWA, the heating process is active, resulting in temperatures that are higher than RFA. The MWA technique allows for faster ablation times, larger ablation zones, and a reduced heat sink effect compared to RFA (Hinshaw et al; Huang et al.). Potential advantages over RFA were reported as higher intratumoral temperatures, simultaneous inclusion of multiple applicators, treatment of multiple lesions, and less procedural pain (Venook, 2022).

MWA 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. MWA can be performed openly, laparoscopically, percutaneously, or thoracoscopically under sedation, local, or general anesthesia, and is usually performed under image guidance by an interventional radiologist. After identifying the tumor, the rendering provider uses guided imagery to insert a small needle with a probe directly into it. Following probe placement confirmation, a microwave antenna or multiple antennas are connected to a generator. Antenna energy generates tumor friction and local heat coagulates nearby tissue, causing ablation. In tumors larger than 2 cm, several antennas may be utilized to increase MWA's targeted area and reduce operative time. Generally, MWA-ablated cells are replaced by fibrosis and scar tissue. If there is a local recurrence, it typically occurs at the margins and treatment may be repeated as necessary. MWA treatment may (1) limit local tumor growth and prevent recurrence; (2) alleviate symptoms; and (3) extend survival. Complications from percutaneous MWA complications are similar to those reported for RFA and are typically mild, including pain, fever, and transaminase elevation; the risk of liver abscess, bile leak/biloma, ascites/pleural effusion, diaphragm injury, and needle track seeding is all low.

Regulatory Status

The FDA has cleared multiple MWA devices for marketing via the 510(k) process. To clear these devices, the FDA used determinations of substantial equivalence to existing radiofrequency and MWA devices. FDA 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 MWA of (unspecified) soft tissues. 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

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- Microsulis Medical's (now part of AngioDynamics) Acculis® Accu2i
- NeuWave Medical's Certus 140™
- 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 MWA of primary or metastatic liver and lung tumors; it does not address other ablative therapies or MWA for the treatment of splenomegaly or ulcers for cardiac applications, or as a surgical coagulation tool.

Other Related Policies: *Radiofrequency Ablation of Primary or Metastatic Liver Tumors Policy No. 391*

COVERAGE POLICY

A. Primary or Metastatic Hepatic Tumors

MWA of primary or metastatic hepatic tumors may be considered medically necessary when **ALL** of the following criteria are met:

1. The tumor is unresectable due to the location or extent of the lesion(s) and/or comorbid conditions. Documentation that the member is not an open surgical candidate or unable to tolerate an open surgical resection; **AND**
2. A single tumor of ≤ 5 cm or up to 3 nodules ≤ 3 cm each.

B. Metastatic Lung Tumors

MWA of primary or metastatic lung tumors may be considered medically necessary when **ALL** of the following criteria are met:

1. The tumor is unresectable due to the location or extent of the lesion(s) and/or comorbid conditions. Documentation that the member is not an open surgical candidate or unable to tolerate an open surgical resection; **AND**
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. MWA 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 MWA therapy of patients with unresectable primary or metastatic solid tumors, other than hepatocellular or pulmonary, is comprised of systematic reviews and case series. There is insufficient high-quality evidence, such as well-designed RCTs, comparative studies, and systematic reviews, with relevant outcomes in overall

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survival (OS), 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

HCC treatment options include surgical resection or liver transplantation, or nonsurgical procedures such as ablative therapies (RFA, MWA, cryoablation, percutaneous ethanol or acetic acid injection), transarterial chemoembolization (TACE), radiation therapy, and systemic therapy. Hepatectomy, the partial removal of the liver, is regarded the gold standard. However, most hepatic tumors are unresectable at the time of diagnosis due to their anatomical location, size, number of lesions, or underlying liver reserve. Treatment options are based on staging, resectability, presence of comorbidities, and performance status.

Numerous RCTs have compared MWA to RFA in patients with primary hepatic tumors (Vietti Violi et al, 2018; Shibata et al, 2002; Yu et al, 201; Abdelaziz et al, 2014; Chong, 2020); one RCT has compared MWA to resection. 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 (Chong et al. 2020; Zheng et al. 2020; Vietti Violi et al. 2018; Zaitoun et al. 2021). Many of these studies were included into the systematic reviews and meta-analyses outlined below.

Zaitoun et al. (2021) compared the safety and efficacy of combination therapy with TACE and MWA (n=89) vs TACE (n=84) or MWA (n=92) used alone in patients with 3 to 5 cm solitary HCC lesions. TACE was performed first, followed by MWA after 15 days. The mean tumor size in the TACE, MWA, and combination groups was 3.6 cm, 3.9 cm, and 3.7 cm, respectively (p=.053). At one month, 86.5% of patients receiving combination therapy had a complete response, compared to 54.8% of TACE patients and 56.5% of MWA patients. Patients who received combination therapy had a significantly lower 12-month recurrence rate and a significantly higher 3-year OS rate (69.6%). In the combined, TACE, and MWA groups, minor adverse events (e.g., nausea, vomiting, abdominal pain, and low-grade fever) occurred in 24.7%, 47.6%, and 38% of patients, respectively. Severe liver dysfunction occurred in 1 patient in the combination group and 3 in the TACE group. Two MWA patients were found to have tumor seeding. The concentrations of alpha-fetoprotein decreased in 75%, 63%, and 48% of patients who received combined therapy, MWA, or TACE, respectively.

Chong et al. (2020) published an RCT that compared MWA to RFA in 93 patients with HCC with up to 3 lesions of 5 cm or smaller. The average tumor size in the MWA group was 3.1 cm, while it was 2.8 cm in the RFA group. The rate of complete ablation at 1 month did not differ significantly between MWA (95.7%) and RFA (97.8%). OS rates up to 5 years and disease-free survival rates up to 3 years were comparable between groups. However, because the sample size was calculated using rates of complete ablation at 1 month, the study may not have been sufficiently powered to detect differences in OS or disease-free survival.

Vietti Violi et al. (2018) conducted a RCT to compare the efficacy of RFA and MWA in treating inoperable HCC in 152 patients with up to three lesions of 4 cm or smaller. At 2 years, 6% (6/98) of MWA-treated lesions had local tumor progression compared to 12% (12/104) of RFA-treated lesions (RR1.62; 95% CI: 0.66 to 3.94; P=0.27). There were few complications and no treatment-related deaths in either group. OS at 2 years did not differ significantly between groups. Because some patients did not receive the assigned treatment or were lost to follow-up, the analyses were performed on a per-protocol basis rather than on an intention-to-treat basis. Furthermore, the researchers intended to evaluate the effects of the treatments on larger lesions, but only a few patients had lesions larger than 4 cm, making a detailed analysis impossible. A five-year follow-up period is planned for this study.

Systematic Review and Meta-Analysis

For patients with liver cancers, MWA has been studied in several systematic reviews:

- MWA vs. RFA: Dou et al. (2022); Chinnaratha et al. (2016)
- MWA vs. resection: Glassberg et al. (2019)
- MWA vs. a range of therapies, including RFA and resection: Cui et al, 2020.

Dou et al. (2022) published a systematic review and meta-analysis comparing the safety and efficacy of MWA and RFA in HCC patients that included 28 cohort studies and 5 RCTs. There was no significant difference in disease-free survival, OS, or major complications between the two groups. MWA demonstrated a lower rate of local tumor progression than RFA in the cohort studies. The reviewers concluded that there were several differences between the

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included studies (e.g., equipment used and operator experience) and that additional high-quality RCTs are required to draw a definitive conclusion regarding the advantages and disadvantages of MWA and RFA in this patient population.

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.

Cui et al. (2020) published a systematic review and meta-analysis of MWA versus other treatment modalities. The analysis included four RCTs: three RCTs compared MWA to RFA (Yu et al., 2017; Shibata et al., 2002; Abdelaziz et al., 2014) and one compared MWA to TACE (Abdelaziz et al., 2014). The remaining 11 trials compared MWA to RFA (n=8), resection (n=2), or ethanol ablation (n=1). Meta-analyses were not performed for MWA versus TACE or ethanol ablation because these comparisons were only examined in one study each. Meta-analyses of studies comparing MWA to RFA found no difference in 3-year survival, 5-year survival, 1-year local tumor progression, 3-year progression-free survival, or major complications. A meta-analysis of two nonrandomized studies comparing MWA to resection reported no difference in 3-year OS; however, this comparison is limited by the small number of studies included and the lack of RCTs. The reviewers concluded that MWA was as safe and effective as RFA, but additional high-quality clinical trials are required to validate MWA's superiority.

Chinnaratha et al. (2016) conducted a meta-analysis of RCTs and observational studies that compared the efficacy and safety of RFA to MWA in patients with primary HCC from January 1980 to May 2014. The risk of local tumor progression (LTP) was the primary outcome, with complete ablation, OS, and major adverse events as secondary outcomes. Ten studies were included, two of which were prospective and eight of which were retrospective. Overall, the LTP rate was 14% (176/1298). The LTP rates did not differ between RFA and MWA. The rates of complete ablation, one- and three-year OS, and major adverse events were comparable between the two modalities ($p > 0.05$ for all). LTP rates were lower with MWA for larger tumors, according to subgroup analysis. There was no evidence of significant publication bias or interstudy heterogeneity for any of the measured outcomes.

Glassberg et al. (2019) conducted a systematic review comparing MWA to hepatic resection in HCC or metastatic liver cancer patients. One RCT (Xu et al 2015) was included, and the remaining studies (n=15) were observational. MWA patients had a significantly higher risk of local tumor recurrence than resection patients. OS at one year did not differ between MWA and resection, but it was significantly higher in patients who had received resection at three and five years. MWA had fewer overall and major complications than resection. MWA also reduced operative time, intraoperative blood loss, and hospital length of stay significantly. Some studies included unresectable patients in the MWA treatment arm, but the reviewers were unable to calculate the number of unresectable patients or conduct subgroup analyses by resectable vs unresectable tumors due to limited reporting and patient preference influencing which treatment was used. MWA was typically reserved for patients with smaller and/or deeper tumors, more comorbidities, and a preference for a less invasive procedure. The reviewers concluded that MWA can be an effective and safe alternative to hepatic resection in patients that cannot undergo a surgical resection; however, more research is needed to identify the population that would benefit most from MWA.

Unresectable Primary or Metastatic Lung Tumors

Macchi et al. (2017) conducted an RCT comparing MWA to RFA for lung tumors. The study is a controlled prospective multicenter random trial with 1:1 randomization, with 52 patients in stage IV disease (mean age 69, range 40–87). The patients were randomly assigned to two distinct subgroups: MWA and RFA. The OS and complication rates were used to assess technical and clinical success in each group. Participants had a single tumor up to 5 cm in size and up to 5 metastases up to 5 cm in size. At baseline, the mean tumor size in the MWA group was 2.21 cm and 1.64 cm in the RFA group. At 6 and 12 months, mortality rates did not differ between groups, but complications were significantly lower in the MWA group. There were not significant differences between the two groups in terms of survival time, while the pain level in MWA group was significantly less than in RFA group ($1.79 < 3.25$). In terms of efficacy and safety, the authors found that RFA and MWA are both acceptable options for the treatment of lung tumors. However, compared to RFA therapy, MWA reduced intraprocedural pain and substantially reduced tumor mass. The study's limitations

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include a small sample size, a lack of reporting on blinding, and a relatively short follow-up period. The results were not broken down by tumor size or the number of metastases.

Systematic Review and Meta-Analysis

Three systematic reviews compared MWA versus RFA for the treatment of lung cancer.

Nelson et al. (2019) conducted a systematic review to compile data on local recurrence and adverse events following MWA for primary non-small cell lung cancer or pulmonary metastases. Twelve retrospective observational studies of MWA 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 MWA 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 greatly, with more recent studies and smaller tumors associated with higher rates of treatment efficacy.

Yuan et al. (2019) reported, based on a meta-analysis of observational data, that patients who underwent RFA had a longer OS than those who had MWA. The reviewers indicated that both percutaneous RFA and MWA were effective and had a high safety profile, but that these estimates could not be directly compared because they were derived from different study groups. Various eligibility criteria for patients were utilized in the analysis. The reported data were insufficient for subgroup analyses based on tumor size or number.

Jiang et al. (2018) performed a network meta-analysis to assess the efficacy of various ablation techniques in patients with lung tumors. The analysis did not consider tumor size, stage of disease, or primary versus metastatic disease. At 1, 2, 3, 4, and 5 years, the weighted average OS rates for MWA were 82.5%, 54.6%, 35.7%, 29.6%, and 16.6%, respectively.

National and Specialty Organizations

National Comprehensive Cancer Network (NCCN)

Hepatobiliary Cancers

MWA (along with RFA, cryoablation and percutaneous alcohol injection) is listed as a treatment option for HCC in patients who are not candidates for potential curative treatments (e.g., resection and transplantation) and do not have large-volume extrahepatic disease in NCCN guidelines on hepatobiliary cancers (v.2. 2022). Ablation should only be considered when tumors can be accessed percutaneously, laparoscopically, or surgically. 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."

Non-Small Cell Lung Cancer (NSCLC)

The guidelines on NSCLC (v.2022) do not mention MWA and state, "for medically operative disease, resection is the preferred local treatment modality (other modalities include SABR, thermal ablation such as radiofrequency ablation, and cryotherapy)."

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."

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Neuroendocrine and Adrenal Tumors

NCCN guidelines on neuroendocrine tumors (v.1.2022) state that cytoreductive surgery or ablative therapies (e.g., 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 energy, can be considered for oligometastatic liver disease, generally up to 4 lesions each smaller than 3 cm.

Kidney Cancer

NCCN 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.

Breast Cancer

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

The **National Institute for Health and Care Excellence (NICE)** published guidance (2022) on MWA for primary or metastatic cancer in the lungs. The guidelines recommended the following:

- 'Evidence on the safety of MWA for treating primary lung cancer and metastases in the lung is adequate but shows it can cause infrequent serious complications. Evidence on its efficacy shows it reduces tumor size. But the evidence on improvement in survival, long-term outcomes and quality of life is limited in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.'
- Additional research should consist of RCTs and illness registry studies. It should report patient selection, disease progression, and quality of life, and consider the efficacy of oligometastatic disease management in patients.

An Interventional procedures guidance (IPG553), in 2016 to replace the interventional procedures guidance on MWA for the treatment of liver metastases (IPG406). According to the revised guidance:

- The current evidence on the safety and efficacy of MWA for treating liver metastases presents no significant safety concerns, and the evidence on tumor ablation is sufficient. This approach may be utilized if standard preparations for clinical governance, consent, and audit are in place.
- A multidisciplinary hepatobiliary cancer team should select patients.
- Additional research would benefit the patient selection process for this treatment. This should include the location and type of primary tumor being treated, the treatment intention (palliative or curative), imaging techniques used to assess the procedure's efficacy, long-term outcomes, and survival.

NICE (2007) published MWA recommendations for hepatocellular carcinoma, which stated 'Current evidence on the safety and efficacy of MWA for the treatment of hepatocellular carcinoma appears sufficient to warrant the use of this therapy, given that consent, audit, and clinical governance are in place.' The guideline also stated that there are no major concerns about MWA's efficacy, but that long-term survival data is lacking.

The **American Urological Association (AUA)** updated its guidelines on renal mass and localized renal cancer, noting that both RFA and cryoablation may be offered as options for patients who choose thermal ablation (Conditional Recommendation; Evidence Level: Grade C). Thermal ablation can be considered as an alternative approach in the treatment of T1a solid renal masses *less than* 3 cm. Percutaneous techniques are preferred in these patients (Moderate Recommendation; Evidence Level: Grade C). The guidelines do not specifically address MWA (Campbell et al, 2021).

SUPPLEMENTAL INFORMATION

N/A

CODING & BILLING INFORMATION

CPT Codes

CPT	Description
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
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
50592	Ablation, 1 or more renal tumor(s), percutaneous, unilateral, radiofrequency
53899	Unlisted procedure, urinary system
60699	Unlisted procedure, endocrine system
76940	Ultrasound guidance for, and monitoring of, parenchymal tissue ablation
77013	Computed tomography guidance for, and monitoring of, parenchymal tissue ablation

HCPCS Code

HCPCS	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

12/14/2022 New policy. IRO Peer Review: 12/14/2022. Practicing physician board-certified in Radiation Oncology.

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Government Agency

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Hepatocellular carcinoma

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