



# Medical Coverage Policy

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## Amplitude-Modulated Radiofrequency Electromagnetic Fields Therapy

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### INSTRUCTIONS FOR USE

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for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

## Overview

This Coverage Policy addresses intrabuccal, systemic delivery of amplitude-modulated, radiofrequency electromagnetic fields therapy for cancer treatment.

## Coverage Policy

**Amplitude-modulated, radiofrequency electromagnetic fields therapy (HCPCS E0767) is considered experimental, investigational or unproven.**

## Coding Information

### Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

### Considered Experimental/Investigational/Unproven:

HCPCS Codes	Description
E0767	Intrabuccal, systemic delivery of amplitude-modulated, radiofrequency electromagnetic field device, for cancer treatment, includes all accessories

**\*Current Procedural Terminology (CPT®) ©2025 American Medical Association: Chicago, IL.**

## General Background

Low-energy radio frequency electromagnetic fields (EMFs) penetrate cells and can influence multiple cell biological processes via non-thermal effects. It is hypothesized that amplitude-modulation frequencies that alter the behavior of electrically excitable cells may also disrupt the proliferation of cancer cells.

Two existing medical devices provide systemic exposure to low-power Low-Energy Amplitude-Modulated Radiofrequency Electromagnetic Fields (LEAM RF EMFs) with a carrier wave frequency of 27.12 MHz: the P1 (TheraBionic) and the AutEMdev (Autem Therapeutics). These small battery-operated devices emit extremely low-power EMFs, each delivering less than 100 mW into a spoon-shaped stainless-steel antenna that is placed into the individual's mouth. The resulting whole body-specific absorption rate of 1.77 mW/kg lies far below international safety limits and is too low to cause detectable heating. The device power is about 1,000 times lower than that of a mobile phone and 100,000 times lower than that of thermal tumor ablation devices.

Low-Energy Amplitude-Modulated Radiofrequency Electromagnetic Fields (LEAM RF EMF) technology differs from so-called Tumor Treating Fields because it uses different frequency ranges, uses electromagnetic rather than electric fields, and delivers energy systemically rather than locally (Tuszynski, et al., 2022).

### **U.S. Food and Drug Administration (FDA)**

The TheraBionic device received Breakthrough Designation in 2019 and Humanitarian Device Exemption (HDE) approval on September 26, 2023 (Thera Bionic P1 – H220001) (TheraBionic Inc., North Carolina). The TheraBionic P1 medical device is intended for the treatment of individuals  $\geq 18$  years of age with advanced hepatocellular carcinoma (HCC) who fail first- and second-line therapy.

AutEMdev™/AutEMsys™ (Autem Therapeutics, New Hampshire, USA) has not yet received regulatory approval and is not available for commercial distribution.

### **Literature Review**

There is a paucity of well-designed, published peer-reviewed scientific trials addressing the safety and effectiveness of amplitude-modulated radiofrequency electromagnetic fields (AM RF-EMF) therapy on long-term health outcomes including mortality.

Costa et al. (2011) assessed the safety and effectiveness of the intrabuccal administration of very low levels of electromagnetic fields amplitude modulated at HCC-specific frequencies in 41 individuals with advanced HCC and limited therapeutic options. The brand or manufacturer of the devices used is not specified.

- Inclusion criteria: eligible for surgical resection or had disease progression after surgical or locoregional therapies or had disease progression after chemotherapy or sorafenib therapy. Individuals with measurable, inoperable HCC were eligible for enrolment. Previous local or systemic treatments were allowed as long as they were discontinued at least 4 weeks before enrolment. Inclusion criteria included Eastern Cooperative Oncology Group performance status of 0, 1, or 2 and biopsy-confirmed HCC. Also allowed were individuals with no pathological confirmation of HCC with a level of  $\alpha$ -fetoprotein higher than 400 ng ml<sup>-1</sup> and characteristic imaging findings as assessed by multi-slice computer tomography (CT) scan or intravenous contrast ultrasound (US).
- Exclusion criteria included confirmed or suspected brain metastasis, Child–Pugh C, previous liver transplant, and pregnancy.
- Three-daily 60-min outpatient treatments were administered until disease progression or death. Imaging studies were performed every 8 weeks. The primary efficacy end point was progression-free survival  $\geq 6$  months. Secondary efficacy end points were progression-free survival and overall survival.
- The author reported treatment was well tolerated and there was no NCI grade 2, 3 or 4 toxicities. In all, 14 individuals (34.1%) had stable disease for more than 6 months. Median progression-free survival was 4.4 months, and median overall survival was 6.7 months. There were three partial and one near complete responses. Three of the four partial responses were observed in individuals with biopsy-proven HCC.
- The author noted a study limitation is that only 19 of the 41 individuals had biopsy-proven HCC, and the others were diagnosed by clinical criteria.
- The authors concluded that “the encouraging findings from this study warrant a randomized study to determine the impact of AM EMFs on OS and time to symptomatic progression”.

Blackstock et al. (2021) reported a study including 18 individuals from multiple centers and 41 individuals from the Costa et al. (2011) study.

- Of the 18 individuals, twelve individuals had Child-Pugh A, four individuals Child-Pugh B, and two individuals had Child-Pugh C liver function. Half of the individuals had serum Alpha-Fetoprotein (AFP) levels greater than 400 ng/mL. Fifteen (83.3%) individuals had evidence of disease progression and all individuals except for one had received at least one systemic therapy prior to initiation of treatment with the TheraBionic device. Fifty-nine individuals receiving TheraBionic treatment were included in these analyses.
- The median overall survival was 6.72 months. Only grade 1 mucositis and fatigue were reported by individuals using the device, even among Child-Pugh B and C individuals. No individuals discontinued treatment because of adverse events. (Published online and not available via PubMed.)

The use of AM RF-EMF via the TheraBionic® device has been proposed in other cancer types, although the device does not have FDA approval outside of use in HCC. Evidence from three individual case reports demonstrated early clinical feasibility and potential antitumor activity of AM RF-EMF. The first case, a 38-year-old with recurrent gliosarcoma/glioblastoma after failure of surgery, radiation, chemotherapy, immunotherapy, and targeted therapy, exhibited both clinical and radiographic improvement within six weeks of initiating daily AM RF-EMF treatment. MRI demonstrated reduced enhancement consistent with treatment response, and the individual self-reported functional gains. No adverse events related to AM RF-EMF were reported; treatment was discontinued after three months due to intracranial bleeding determined to be unrelated to therapy (Jimenez et al., 2025). A second case involved a 47-year-old with multiply recurrent, 1p/19q-codeleted oligodendroglioma following multiple surgeries, chemotherapy regimens, and radiation. Use of glioblastoma-specific frequencies three times daily in combination with ongoing bevacizumab resulted in radiographically stable disease on MRI after two months of treatment. Mild, transient oral discomfort was the only reported side effect. (Jimenez et al., 2025). The third case involved an individual with triple-negative breast cancer and a large calvarial/brain metastatic lesion, daily exposure to breast-cancer-specific modulation frequencies resulted in substantial radiologic regression of the intracranial tumor. MRI demonstrated decreased tumor size, reduced intracranial extension, and resolution of mass effect. The clinical benefit persisted for approximately 11 months, exceeding the typical median survival (< 4 months) for individuals with brain metastases from triple-negative breast cancer. No treatment-related adverse events were reported (Sharma et al., 2019). While these findings are promising, the evidence is limited to individual compassionate-use cases and therefore cannot establish efficacy or generalize to broader populations. Controlled clinical trials are necessary to determine treatment effectiveness, durability of response, optimal treatment parameters, and patient selection criteria.

### **Professional Societies/Organizations**

The National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology on Hepatocellular Carcinoma (Version 2.2025 — October 22, 2025) does not address amplitude-modulated radiofrequency electromagnetic fields therapy.

The American Association for the Study of Liver Diseases (AASLD) Practice Guidance on Prevention, Diagnosis, and Treatment of Hepatocellular Carcinoma does not address amplitude-modulated radiofrequency electromagnetic fields therapy (Singal, et al, 2023).

## **Health Equity Considerations**

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

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## Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	<ul style="list-style-type: none"> <li>• No clinical policy statement changes.</li> </ul>	4/15/2026
Initial Review	<ul style="list-style-type: none"> <li>• New policy statement added</li> </ul>	7/15/2025

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