Medical Coverage Policy

Effective Date.....07/15/2025
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Coverage Policy Number..... 0581

Amplitude-Modulated Radiofrequency Electromagnetic Fields Therapy

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Related Coverage Resources

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers

must use the most appropriate codes as of the effective date of the submission. Claims submitted 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.

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.

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 patient'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 persons ≥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 patients 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. Patients 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 patients with no pathological confirmation of HCC with a level of *x*-fetoprotein higher than 400 ng ml^{-1} and characteristic imaging findings as assessed by multislice 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 ≥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 patients (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 patients with biopsy-proven HCC.
- The author noted a study limitation is that only 19 of the 41 patients 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 patients from multiple centers and 41 patients from the Costa et al. (2011) study.

- Of the 18 patients, twelve patients had Child-Pugh A, four patients Child-Pugh B, and two patients had Child-Pugh C liver function. Half of the patients had serum Alpha-Fetoprotein (AFP) levels greater than 400 ng/mL. Fifteen (83.3%) patients had evidence of disease progression and all patients except for one had received at least one systemic therapy prior to initiation of treatment with the TheraBionic device. Fifty-nine patients 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 patients using the device, even among Child-Pugh B and C patients. No patients discontinued treatment because of adverse events. (Published online and not available via PubMed.)

Professional Societies/Organizations
The National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology on Hepatocellular Carcinoma (Version 4.2024 — January 10, 2025) does not address amplitude-modulated radiofrequency electromagnetic fields therapy.

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	No National Coverage Determination found	
LCD		No Local Coverage Determination found	

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

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

References

1. Autem Therapeutics. Accessed Feb 2025. Available at URL address: https://www.autemtherapeutics.com/

2. Blackstock AW, et al. Safety and Efficacy of amplitude-modulated radiofrequency electromagnetic fields in advanced hepatocellular carcinoma. Published online: 4open, 4 (2021) 3. DOI: https://doi.org/10.1051/fopen/2021003

3. Capareli F, Costa F, Tuszynski JA, Sousa MC, Setogute YC, et al. Low-energy amplitude-modulated electromagnetic field exposure: Feasibility study in patients with hepatocellular carcinoma. Cancer Med. 2023 Jun;12(11):12402-12412 (AutEMdev™ device, Autem Therapeutics).

4. Clinicaltrials.gov. Accessed Feb 2025. Available at URL address: https://clinicaltrials.gov/study/NCT04797884

5. Costa FP, de Oliveira AC, Meirelles R, Machado MC, Zanesco T, et al. Treatment of advanced hepatocellular carcinoma with very low levels of amplitude-modulated electromagnetic fields. Br J Cancer. 2011 Aug 23;105(5):640-8.

6. Jimenez H, Wang M, Zimmerman JW, Pennison MJ, Sharma S, et al. Tumour-specific amplitude-modulated radiofrequency electromagnetic fields induce differentiation of hepatocellular carcinoma via targeting Cav3.2 T-type voltage-gated calcium channels and Ca2+ influx. EBioMedicine. 2019 Jun;44:209-224.

7. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology NCCN Guidelines®. Hepatocellular Carcinoma. Version 4.2024 — January 10, 2025. Accessed Jan 2025. Available at URL address: https://www.nccn.org/professionals/physician_gls/default.aspx

8. TheraBionic. Accessed Feb 2025. Available at URL address: https://www.therabionic.com/ https://www.therabionic.com/news-and-research

9. Tuszynski JA, Costa F. Low-energy amplitude-modulated radiofrequency electromagnetic fields as a systemic treatment for cancer: Review and proposed mechanisms of action. Front Med Technol. 2022 Sep 8;4:869155.

10. U.S. Food and Drug Administration (FDA). Humanitarian Device Exemption (HDE). TheraBionic P1. September 26, 2023. H220001. Accessed Feb 2025. Available at URL address: https://www.fda.gov/medical-devices/recently-approved-devices/therabionic-p1-h220001 https://www.accessdata.fda.gov/cdrh_docs/pdf22/H220001A.pdf

Revision Details

Type of Revision	Summary of Changes	Date
Initial Review	• New policy statement added	7/15/2025