RMHP Alternating Electric Field Therapy - Tumor Treatment Field Therapy (TTFT)

MCG Health

Ambulatory Care 27th Edition

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Clinical Indications

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TTFT requests for **RMHP Medicare (CareAdvantage and Dual Special Needs Plan (DSNP)** members will be pended. The reviewer will apply the current Medicare Local Coverage Determination and Article guidelines, then the requester will be notified of the determination. See References.

TTFT requests for **RMHP PRIME (Medicaid) and CHP Plus** plan members are non-covered services per Colorado Department of Health Care Policy and Financing (HCPF) guidance. Requests cannot be approved. See References.

- Alternating electric field therapy may be indicated for Individual and Family Plan (IFP) commercial plan members when ALL of the following are present(1)(2)(3)(4)(5)(6)(7):
 - o Age 22 years or older
 - o Glioblastoma, newly diagnosed, as indicated by **ALL** of the following:
 - Administered in combination with temozolomide
 - Postoperative adjuvant treatment needed after completion of chemoradiation and, if feasible, maximal debulking surgery
 - Supratentorial disease
 - o Karnofsky Performance Status (KPS) score of 60 or higher [A]
 - No cardiac pacemaker or implantable defibrillator
 - No deep brain, spinal cord, or vagus nerve stimulator
 - No major skull defect (eg, missing section of calvarium)
 - No metal within brain (eg, aneurysm clip, bullet fragment)
 - No programmable ventriculoperitoneal shunt

Alternatives

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- Alternatives for newly diagnosed glioblastoma include(<u>12</u>)(<u>13</u>):
 - Chemotherapy
 - Palliative care
 - Radiation therapy

Evidence Summary

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Background

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Alternating electric field therapy is delivered by a portable device that creates alternating low-intensity, intermediate-frequency electric fields called tumor treatment fields ("TTFields") that inhibit cell mitosis, interfering with cell division and organelle assembly. The electric field is applied via transducer arrays with electrodes to the surface area above the tumor; computational mapping is used to determine the placement of the electrodes. Patients are advised to wear the device at least 18 hours per day.(14)(15)(16) (EG 2)

Criteria

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For glioblastoma, newly diagnosed, A multicenter, open-label, randomized, phase III trial of 695 adults with supratentorial glioblastoma who were progression free after debulking surgery or biopsy, had undergone standard chemoradiotherapy with temozolomide, and had a mean Karnofsky Performance Status score of 90 (range 60 to 100) evaluated treatment with alternating electric field therapy plus temozolomide maintenance vs temozolomide maintenance only. Interval analysis of 315 patients found, at a median follow-up of 38 months, that combined treatment was associated with an increased median progression-free survival (9.2 months vs 4.0 months, respectively) and overall survival (20.5 months vs 15.6 months, respectively) compared with temozolomide treatment only. The trial was terminated based on the results of the interim analysis. The authors note that the study was limited to patients who had completed radiochemotherapy without progression of disease, excluding patients with poor prognosis; patients with poor performance status were also excluded.(17) (EG 1) At a median follow-up of 40 months, alternating electric field therapy plus temozolomide vs temozolomide alone continued to be associated with increased median progression-free survival (6.7 months vs 4.0 months, respectively) and overall survival (20.9 months vs 16.0 months, respectively).(18) (EG 1) An expert consensus guideline supports alternating electric field therapy as a treatment option for newly diagnosed glioblastoma in combination with temozolomide and radiation therapy for patients with supratentorial disease and a Karnofsky Performance Status score of 60% or greater.(12) (EG 2)

Inconclusive or Non-Supportive Evidence

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For glioblastoma, recurrent, A randomized phase III trial of 237 patients (median Karnofsky Performance Status score of 80) with recurrent supratentorial glioblastoma comparing alternating electric field therapy and physician's best choice chemotherapy found, at a median follow-up of 39 months, that there was no significant difference in median 1-year overall survival and 6-month progression-free survival between the treatment groups; however, patients treated with alternating electric field therapy reported fewer gastrointestinal, hematologic, and infectious side effects as compared with patients treated with chemotherapy. The authors noted that the study was designed to demonstrate superiority of the intervention; the findings were also limited by the hete rogeneous patient population and prior exposures to chemotherapy. (19) (EG1) An expert consensus guideline indicates that alternating electric field therapy is a treatment option for patients with recurrent glioblastoma. (12) (EG2)

For malignant pleural mesothelioma, A multicenter single-arm phase II trial of 80 patients with unresectable malignant pleural mesothelioma treated with tumor treatment fields combined with chemotherapy (pemetrexed plus platinum-based therapy (cisplatin or carboplatin)) found, at a median follow-up of 12.5 months, median overall and progression-free survival of 18.2 months and 7.6 months, respectively. However, the authors noted that the lack of a control group limited the results, and larger randomized trials were recommended.(20) (EG 2) An expert consensus guideline does not include alternating electric field therapy as a treatment option for malignant pleural mesothelioma.(21) (EG 2)

Reviewer Guidance

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Other Uses The use of TTFT for any indications other than newly diagnosed GBM will be denied as not reasonable and necessary. Coding Guidelines Code E0766 describes devices that generate electromagnetic fields utilized in the treatment of cancer. The electromagnetic energy generated is transmitted to the body by means of surface electrodes or transducers. This code is inclusive of all associated supplies necessary for the effective use of code E0766 including, but not limited to, transducers/surface electrodes, lead wires, adhesive patches, connectors, conductive gel and skin preps. Code A4555 is not valid for billing to Medicare. If code A4555 is billed, it will be denied as an invalid code.

Policy History

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Policy created 8/27/2021 with MCG 25th edition provision of new A-0930. Retired RMHP-AC-6050.

7/8/2022 Annual review and updated references.

5/12/2023 Annual review and updates.

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The Center for Medicare and Medicaid Services (CMS) Local Coverage Determination (LCD) Tumor Treatment Field Therapy (TTFT) (L34823) and Policy Article (A52711)Original Effective Date for services performed on or after 10/01/2015, Revision Effective Date for services performed on or after 01/01/2020, both reviewed 5/12/2023.

The Colorado Department of Health Care Policy and Financing (HCPF) Health First Colorado (Medicaid) fee schedule and the Durable Medical Equipment (DME) Upper Payment Limit Fee Schedule. TTFT HCPCS codes not listed when reviewed 5/12/2023. Most current published CHP+ fee schedule is for 2021, use Health First Colorado.

References

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 Context Link 1]
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Footnotes

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[A] The Karnofsky Performance Status (KPS) scale rates a person's ability to function independently and is used to determine the appropriate treatment and prognosis. The index ranges from 0 to 100: A score of 100 means the patient is fully active and without complaints; 90 means the patient is able to carry on normal activity but has minor symptoms of disease; 80 means the patient can carry on normal activity with effort; 70 means the patient can care for self but is unable to do normal activity or active work; 60 means the patient is able to do self-care but needs occasional assistance; 50 means the patient requires frequent medical care and assistance; 40 means the patient needs special care and assistance; 30 means the patient is severely limited in activities and may require hospitalization; 20 means the patient is very ill and requires active supportive care; 10 means the patient is moribund; 0 means the patient is dead.(8) [A in Context Link 1]

[B] Patients with healed burr holes and craniotomy sutures are eligible for alternating electric field therapy.(10) [B in Context Link 1]

Codes

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CPT®: 77299

HCPCS: A4555, E0766

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