Overview
The purpose of this document is to describe the guidelines AllWays Health Partners utilizes to determine the medical necessity for electric tumor treating fields therapy (ETTFs) (e.g. Optune® device) to treat supratentorial glioblastoma multiforme (GBM). The treating specialist must request prior authorization for the procedure.

Coverage Guidelines
Initial Treatment
The use of an FDA approved device to generate tumor treating fields therapy may be considered medically necessary for up to three months when documentation confirms ALL the following criteria:
1. The member is 22 years of age or older;
2. The member has histologically or radiologically-confirmed newly-diagnosed supratentorial GBM (also known as World Health Organization [WHO] grade IV astrocytoma);
3. The member has a Karnofsky Performance Status (KPS) score of ≥ 70;
4. The member is receiving chemotherapy with temozolomide;
5. The member has received and completed standard treatments that included debulking surgery (when feasible and clinically appropriate), and radiation therapy;
6. The member understands device use and is willing to wear the device at least 18 hours daily

Treatment of Recurrence
The use of an FDA approved device to generate ETTFs for members with histologically or radiologically-confirmed recurrence GBM may be considered medically necessary for up to three months when initial criteria have been met, and documentation confirms ALL the following criteria:
1. The device is being used as a monotherapy;
2. The member has received and completed chemotherapy with temozolomide;
3. The member wears the device at least 18 hours daily

Exclusions
The use of devices to generate ETTFs is considered investigational, unproven, and not medically necessary when the criteria above are not met and for all other indications.
Definitions

**Electric Tumor Treatment Field Therapy (ETTFs),** Also known as Tumor-treating fields, electric tumor treatment field therapy, and TTFields. TTF is a noninvasive technology intended to treat glioblastoma on an outpatient basis and at home using electrical fields. It is founded on the principle that low intensity, intermediate frequency electric currents delivered to the malignant tumor site by insulated electrodes placed on the skin surface can disrupt rapid cell division and may destroy proliferating cells in brain tumors.

**Glioblastoma Multiforme:** A fast-growing type of central nervous system tumor that forms from glial (supportive) tissue of the brain and spinal cord and has cells that look very different from normal cells. Glioblastoma multiforme usually occurs in adults and affects the brain more often than the spinal cord. Also called GBM, glioblastoma, and grade IV astrocytoma.

**Karnofsky Performance Status (KPS):** A standard way of measuring the ability of cancer patients to perform ordinary tasks. KPS scores range from 0 to 100. A higher score means a person is better able to carry out daily activities. KPS may be used to determine a patient’s prognosis, to measure changes in a patient’s ability to function, or to decide if a patient could be included in a clinical trial.

**Supratentorial:** The upper portion of the brain comprised of the cerebrum and the diencephalon.

**Karnofsky Performance Status Score**

A 10 point scale used by healthcare providers to quickly evaluate how an individual is feeling. This scale is used within the clinical guidelines’ algorithm.

- 100 Able to work. Normal; No complaints; No evidence of disease.
- 90 Able to work. Able to carry on normal activity; Minor symptoms.
- 80 Able to work. Normal activity with effort; some symptoms.
- 70 Independent; not able to work. Cares for self; Unable to carry on normal activity.
- 60 Disabled; dependent. Requires occasional assistance; cares for most needs.
- 50 Moderately disabled; dependent. Requires considerable assistance and frequent care.
- 40 Severely disabled; dependent. Requires special care and assistance.
- 30 Severely disabled. Hospitalized, death not imminent.
- 20 Very sick. Active supportive treatment needed.
- 10 Moribund. Fatal processes are rapidly progressing.

**CPT/HCPC Codes**

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<tr>
<th>Authorized CPT/HCPCS Codes</th>
<th>Code Description</th>
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<tr>
<td>A4555</td>
<td>Electrode/transducer for use with electrical stimulation device used for cancer treatment, replacement only</td>
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**Effective**

March 2021: Effective Date.
References


