

**Medical Policy
Tumor Treating Fields**

	Commercial and Connector/ Qualified Health Plans	MassHealth
Authorization required	X	
No Prior Authorization		
Not Covered		X

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 . 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 glioblastoma (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 of supratentorial glioblastoma 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. Surgical and radiation options have been exhausted;
4. 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: 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 multiforme, 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

Authorized CPT/HCPCS Codes	Code Description
A4555	Electrode/transducer for use with electrical stimulation device used for cancer treatment, replacement only

Effective

April 2022: Annual Review. Overview and Coverage sections changed to edit name of tumor to “glioblastoma”. Under Treatment Recurrence, added requirement “surgical and radiation options have been exhausted”. References updated.

March 2021: Effective Date.

References

Burri SH, Gondi V, Brown PD, Mehta MP. The evolving role of tumor treating fields in managing glioblastoma: guide for oncologists. *Am J Clin Oncol*. 2018; 41(2):191-196.

Hayes, Inc. Hayes Health Technology Assessment. Tumor Treating Fields (Optune) for Treatment of Glioblastoma. Lansdale, PA: Hayes, Inc.; December 2019.

Karnofsky Performance Status Scale: Karnofsky Performance Status Scale. *Emedicine.medscape.com*. <https://emedicine.medscape.com/article/2172510-overview>. Published 2014.

Kim CY, Paek SH, Nam DH, et al. Tumor treating fields plus temozolomide for newly diagnosed glioblastoma: a sub-group analysis of Korean patients in the EF-14 phase 3 trial. *J Neurooncol*. 2020 Feb;146(3):399-406.

Marenco-Hillebrand L, Wijesekera O, Suarez-Meade P, et al. Trends in glioblastoma: outcomes over time and type of intervention: a systematic evidence based analysis. *J Neurooncol*. 2020 Apr;147(2):297-307.

Mrugala MM, Engelhard HH, Dinh Tran D, et al. Clinical practice experience with NovoTTF-100A™ system for glioblastoma: The Patient Registry Dataset (PRiDe). *Semin Oncol* 2014; 41 Suppl 6:S4.

National Cancer Institute (NCI) Dictionary of Cancer Terms. Available at: <https://www.cancer.gov/publications/dictionaries/cancer-terms>. Accessed November 20, 2021.

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Central Nervous System Cancers. Version 2.2021 – September 8, 2021.

Optune Treatment. 2018. Available at: <https://www.optune.com/>. Accessed December 1, 2020.

Ram Z, Kim CY, Hottinger AF, et al. Efficacy and Safety of Tumor Treating Fields (TTFields) in Elderly Patients with Newly Diagnosed Glioblastoma: Subgroup Analysis of the Phase 3 EF-14 Clinical Trial. *Front Oncol*. 2021 Sep 27;11:671972. doi: 10.3389/fonc.2021.671972. PMID: 34692470; PMCID: PMC8526342.

Regev O, Merkin V, Blumenthal DT, et al. Tumor-Treating Fields for the treatment of glioblastoma: a systematic review and meta-analysis. *Neurooncol Pract*. 2021 Apr 20;8(4):426-440.

Rulseh AM, Keller J, Klener J, et al. Long-term survival of patients suffering from glioblastoma multiforme treated with tumor-treating fields. *World J Surg Oncol*. 2012; 10:220

Stupp, R., Wong, ET., Kanner, AA., et al. NovoTTF-100A versus physician's choice chemotherapy in recurrent glioblastoma: A randomized phase III trial of a novel treatment modality. *Eur J Cancer*. 2012; 48(14):2192-2202.



Stupp R, Taillibert S, Kanner AA, et al. Maintenance Therapy With Tumor-Treating Fields Plus Temozolomide vs Temozolomide Alone for Glioblastoma: A Randomized Clinical Trial. *JAMA* 2015; 314:2535.

Stupp R, Taillibert S, Kanner A, et al. Effect of Tumor-Treating Fields Plus Maintenance Temozolomide vs Maintenance Temozolomide Alone on Survival in Patients With Glioblastoma: A Randomized Clinical Trial. *JAMA*. 2017; 318:2306.

Taphoorn MJB, Dirven L, Kanner AA, et al. Influence of treatment w/ tumor-treating fields on health-related quality of life of patients w/ newly diagnosed glioblastoma: a secondary analysis of a randomized clinical trial. *JAMA Oncol*. 2018 Apr 1; 4(4):495-504.

Trusheim J, Dunbar E, Battiste J, et al. A state-of-the-art review and guidelines for tumor treating fields treatment planning and patient follow-up in glioblastoma. *CNS Oncol*. 2017 Jan; 6(1):29-43. Epub 2016 Sep 15.