



MEDICAL POLICY STATEMENT OHIO MEDICAID

Policy Name	Policy Number	Date Effective
Tumor Treatment Field Devices for Glioblastoma Multiforme	MM-1224	11/15/2021-10/31/2022
Policy Type		
MEDICAL	Administrative	Pharmacy
		Reimbursement

Medical Policy Statement prepared by CareSource and its affiliates are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CareSource and its affiliates do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

According to the rules of Mental Health Parity Addiction Equity Act (MHPAEA), coverage for the diagnosis and treatment of a behavioral health disorder will not be subject to any limitations that are less favorable than the limitations that apply to medical conditions as covered under this policy.

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A. Subject

Tumor Treatment Field Devices for Glioblastoma Multiforme (GBM)

B. Background

Glioblastoma Multiforme is the most common central nervous system malignancy of the brain in adults, with an average onset age between 55 to 60 years. The incidence rate between 2010 and 2014 was 29.2 per 100,000 in adults, and 5.81 per 100,000 in children. Management of the disease follows a combined-modality approach, including: adjuvant postoperative radiation therapy and adjuvant chemotherapy following initial surgery. Surgery remains the mainstay of treatment in order to remove as much tumor as possible while preserving surrounding brain tissue required for normal brain function. Despite tumor debulking measures, glioblastoma tumors infiltrate surrounding tissues creating little success for removal of the entire tumor (AANS, 2020). Glioblastoma has a high rate of recurrence and poor overall survival rate even with optimum therapy treatments. Most patients live one - two years after initial diagnosis.

Tumor treating field devices (TTF) are the novel method of cancer treatment involving emitting alternating electric fields to disrupt the rapid cell division exhibited by cancer cells. This treatment first became available in 2011 to treat recurrent glioblastoma. TTF is considered safe with no systemic toxicity observed and only mild to moderate side effects (reported in 1-2% of patients) involving the skin beneath transducer arrays. Patients are required to wear the device at least eighteen hours a day for effectiveness and minimum treatment duration is four weeks. Randomized trial results suggest the device improves overall survival when combined with monthly temozolomide in patients with newly diagnosed glioblastoma in the post radiation setting.

C. Definitions

- **Medically Necessary** - "The evaluation of health care services to determine if they are medically appropriate and necessary to meet basic health needs; consistent with the diagnosis or condition and rendered in a cost-effective manner; and consistent with national medical practice guidelines regarding type, frequency, and duration of treatment."
- **Tumor Treatment Fields (TTF)** - Tumor treatment fields are mild electrical fields that vibrate through the skin of the scalp and disturb cancer cells ability to divide, possibly slowing tumor growth and spread.
- **Karnofsky Performance Status (KPS)** - The Karnofsky Performance Scale Index allows patients to be classified as to their functional impairment. This can be used to compare the effectiveness of different therapies and to assess the prognosis in individual patients. The lower the Karnofsky score, the worse the survival for most serious illnesses.
- **Response Assessment in Neuro-Oncology (RANO)** - The Response Assessment in Neuro-Oncology (RANO) working group was established to improve the assessment of tumor response and selection of end points, specifically in the context of clinical trial.



D. Policy

- I. A prior authorization is required for tumor treatment field devices for glioblastoma multiforme and is considered medically necessary when **ALL** of the following criteria have been met:
 - A. The member has a new diagnosis of GBM.
 - B. The member is age 22 years or older
 - C. The member has received initial treatment with surgery (when reasonable).
 - D. TTF therapy is initiated within seven (7) weeks from the last dose of chemotherapy or radiotherapy.
 - E. There is no evidence of progression by Response Assessment in Neuro-Oncology (RANO) criteria.
 - F. The member has a Karnofsky Performance Scale (KPS) index of at least seventy (70).
 - G. TTF treatment will be used for an average of eighteen (18) hours per day.
- II. The following is a list of contraindications for TTL treatment (not all inclusive):
 - A. Cardiac pacemaker or implantable defibrillator
 - B. Deep brain, spinal cord, or vagus nerve stimulator
 - C. Major skull defect (eg, missing section of calvarium)
 - D. Metal within brain (eg, aneurysm clip, bullet fragment)
 - E. Programmable ventriculoperitoneal shunt
 - F. Pregnancy
 - G. Known sensitivity to conductive hydrogels (e.g., gels used on electrocardiogram)
 - H. [ECG] stickers or transcutaneous electrical nerve stimulation [TENS] electrodes)
- III. CareSource considers TTF therapy for GBM only. Treatment of any other tumors is not medically necessary and experimental/investigational.
- IV. The use of enhanced treatment planning software (Novotal) is non-covered because CareSource considers it to be experimental/investigational for **ALL** indications.

E. Conditions of Coverage

F. Related Policies/Rules

G. Review/Revision History

	DATE	ACTION
Date Issued	09/29/2021	New Policy.
Date Revised		
Date Effective	11/15/2021	
Date Archived	10/31/2022	This Policy is no longer active and has been archived. Please note that there could be other Policies that may have some of the same rules incorporated and CareSource reserves the right to follow CMS/State/NCCI guidelines without a formal documented Policy.



H. References

1. Chukwueke U, Wen P, (2019, March). Use of the Response Assessment in Neuro-Oncology (RANO) criteria in clinical trials and clinical practice. Retrieved from CNS Oncology on September 9, 2021.
2. Wen PY, Chang SM, Van den Bent MJ, et al. (2017). Response assessment in neuro-oncology clinical trials. Retrieved from J. Clin. Oncol. 2017;35(21):2439–2449 on September 9, 2021.
3. National Palliative Care Research Center, Karnofsky Performance Status Scale Definitions Rating Criteria. Retrieved from www.npcrc.org on September 9, 2021.
4. Batchelor T., (2019, November). Initial Treatment and prognosis of newly diagnosed glioblastoma in adults. Retrieved from UpToDate on September 9, 2021.
5. Fernandes, Catarina, (2017, September). Current Standards of Care in Glioblastoma Therapy. Retrieved from www.ncbi.nih.gov on September 9, 2021.
6. Tumor Treatment Fields (Optune) for Treatment of Glioblastoma. (2019, December). Retrieved from www.hayesinc.com on September 9, 2021.
7. Glioblastoma Multiforme. (2020, November). Retrieved from the American Association of Neurological Surgeons on September 9, 2021.
8. Food and Drug Administration. OPTUNE™ (NovoTTF™-100A System) Patient Information and Operation Manual. Document QSD-QR-33. Retrieved from www.accessdata.fda.gov on September 9, 2021.

The Medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.

Independent medical review – November 2020