CareSource

# MEDICAL POLICY STATEMENT
# Ohio Medicaid

| Policy Name & Number | Date Effective |
|---|---|
| Tumor Treatment Field Devices for Glioblastoma Multiforme-OH MCD-MM-1224 | 03/01/2024 |
| **Policy Type** | |
| **MEDICAL** | |

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 1-2 years after initial diagnosis.

Tumor treating field devices (TTF) are a 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 clinical 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

- **Glioblastoma (GBM) -** also referred to as a grade IV astrocytoma, is a fast-growing and aggressive brain tumor. It invades the nearby brain tissue, but generally does not spread to distant organs.
- **Medically Necessary -** “Services which are reasonably necessary for the diagnosis or treatment of disease, illness, and injury, and meet accepted guidelines of medical practice. A medically necessary service must be reasonably related to the illness or injury for which it is performed regarding type, intensity, and duration of service and setting of treatment.”
- **Tumor Treatment Fields (TTF) -** 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) -** An index that classifies the functional impairment of patients.. 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) -** A working group established to improve the assessment of tumor response and selection of end points, specifically in the context of clinical trials.

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 (grade IV astrocytoma).
   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 7 weeks from the last dose of chemotherapy or radiotherapy.
   E. The member has a Karnofsky Performance Scale (KPS) index of at least 60.
   F. TTF treatment will be used for an average of 18 hours per day.

II. Continued coverage (beyond first 3 months of therapy) for newly diagnosed GBM and documentation of clinical benefit demonstrates **ALL** of the following:
   A. In-person clinical re-evaluation by treating practitioner
   B. Objective evidence of adherence to therapy, reviewed by treating practitioner
   C. Maintain KPS of at least 60
   D. If KPS is unavailable, then no evidence of progression by Response Assessment in Neuro-Oncology (RANO) criteria

III. The following is a list of contraindications for TTF 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 (eg, gels used on electrocardiogram)
   H. ECG stickers or transcutaneous electrical nerve stimulation (TENS) electrodes

IV. CareSource considers TTF therapy for GBM only. Treatment of any other tumors is not medically necessary and experimental/investigational.

V. 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

N/A

F. Related Policies/Rules
N/A

G. Review/Revision History

| | DATE | ACTION |
|---|---|---|
| **Date Issued** | 09/29/2021 | New Policy. |
| **Date Revised** | 07/06/2022<br>11/8//2023 | Updated references. No changes. Archived Jan.2023.<br>AddedSection II (Continued coverage) . Approved at Committee. |
| **Date Effective** | 03/01/2024 | |
| **Date Archived** | | |

H. References

1. Alternating Electric Field Therapy ACG: A-0930 (AC). (2023). Accessed October 4, 2023. www.careweb.com
2. Batchelor T. Initial Treatment and prognosis of newly diagnosed glioblastoma in adults. UpToDate. Accessed October 4, 2023. www.uptodate.com
3. 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. doi:10.1097/COC.0000000000000395
4. Chukwueke UN, Wen PY. Use of the Response Assessment in Neuro-Oncology (RANO) criteria in clinical trials and clinical practice. *CNS Oncol*. 2019;8(1):CNS28. doi:10.2217/cns-2018-0007
5. Fernandes C, Costa A, Osório L, et al. Current standards of care in glioblastoma therapy. In: De Vleeschouwer S, ed. *Glioblastoma*. Codon Publications; 2017. Accessed October 4, 2023. www.ncbi.nih.gov
6. Glioblastoma multiforme. American Association of Neurological Surgeons. Accessed October 4, 2023. www.aans.org
7. Health Technology Assessment: Tumor Treatment Fields (Optune) for Treatment of Glioblastoma. Hayes; 2019. Reviewed January 5, 2023. Accessed October 4, 2023. www.hayesinc.com
8. Kanderi T, Gupta V. Glioblastoma Multiforme. In: *StatPearls*. Treasure Island (FL): StatPearls Publishing; September 12, 2022. Accessed October 4, 2023.
9. Karnofsky Performance Status Scale definitions rating criteria. National Palliative Care Research Center. Accessed October 4, 2023. www.npcrc.org
10. *OPTUNE™ (NovoTTF™-100A System) Patient Information and Operation Manual*. . Food and Drug Administration. Document QSD-QR-33 Accessed October 4, 2023. www.accessdata.fda.gov
11. Wen PY, Chang SM, Van den Bent MJ, et al Response assessment in neuro-oncology clinical trials. *J Clin Oncol*. 2017;35(21):2439-2449. doi:10.1200/JCO.2017.72.7511

ODM Approved 01/11/2023

*Independent medical review – November 2020*