Medical Policy

Tumor Treating Fields (Optune®)	
MEDICAL POLICY NUMBER	Med_Clin_Ops-024
CURRENT VERSION EFFECTIVE DATE	January 1, 2024
APPLICABLE PRODUCT AND MARKET	*Individual Family Plan:* All Plans *Small Group*: All Plans *Medicare Advantage:* All Plans

Brand New Day/Central Health Medicare Plan develops policies and makes coverage determinations using credible scientific evidence including but not limited to MCG™ Health Guidelines, the ASAM Criteria™, and other third party sources, such as peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and expert opinion as relevant to supplement those sources. Brand New Day/Central Health Medicare Plan Medical Policies, MCG™ Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice. Members may contact Brand New Day/Central Health Medicare Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/Central Health Medicare Plan Medical Policy may contact the Health Plan. Brand New Day/Central Health Medicare Plan policies and practices are compliant with federal and state requirements, including mental health parity laws.

If there is a difference between this policy and the member specific plan document, the member benefit plan document will govern. For Medicare Advantage members, Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), govern. Refer to the CMS website at http://www.cms.gov for additional information.

Brand New Day/Central Health Medicare Plan medical policies address technology assessment of new and emerging treatments, devices, drugs, etc. They are developed to assist in administering plan benefits and do not constitute an offer of coverage nor medical advice. Brand New Day/Central Health Medicare Plan medical policies contain only a partial, general description of plan or program benefits and do not constitute a contract. Brand New Day/Central Health Medicare Plan does not provide health care services and, therefore, cannot guarantee any results or outcomes. Treating providers are solely responsible for medical advice and treatment of members. Our medical policies are updated based on changes in the evidence and healthcare coding and therefore are subject to change without notice. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). MCG™ and Care Guidelines® are trademarks of MCG Health, LLC (MCG).

PURPOSE

The purpose of this policy is to establish the clinical review criteria that support the determination of medical necessity Tumor Treatment Field Therapy.

POLICY

Clinical Review Criteria

Tumor Treating Field (TTF) devices, such as the Optune device, are considered medically necessary for adults with newly diagnosed or recurrent histologically confirmed Glioblastoma Multiforme when ALL of the following criteria are met:

1. Request is for 90 days of therapy.
2. Glioblastoma is in the supratentorial region.
3. Member's age ≥ 22 years.
4. Member has good performance status, as defined by a Karnofsky Performance Status (KPS) rating of ≥ 70.
5. Standard treatment with surgery, radiation and chemotherapy has been completed.
6. Member is receiving Temozolomide (if newly diagnosed).
7. Documentation that the patient understands device use at least 18 hours a day.
8. Subsequent approvals for continuation of TTF for additional 90 days is based upon the following documentation:
   - MRI scan and physical exam has been performed prior to request and document no

evidence of disease progression; and

- KPS score of ≥70; and
- Documentation that the patient has been wearing the device at least 18 hours daily.

9. None of the following contraindications are present:
   a. Implanted medical devices, such as deep brain stimulator, spinal cord stimulators, vagus nerve stimulators, pacemakers, defibrillators or programmable ventriculoperitoneal shunts.
   b. Skull defects, for example, missing bone.
   c. Metal within brain. for example, a bullet fragment or aneurism clip.
   d. Known sensitivity to conductive hydrogels.

*Treatment may be approved until disease progression or for up to 24 months.

Exclusions for ETTF
For all other indications, TTF therapy is considered investigational and not medically necessary

Computer Mapping software (NovoTal™) for planning of TTF therapy is considered investigational and not medically necessary for all indications as there is insufficient evidence to establish the efficacy for long term outcomes of patients receiving TTF therapy.

BACKGROUND

TTF are believed to disrupt the rapid cell division exhibited by cancer cells, with the alternating electrical fields applied to the brain through electrodes placed on the scalp. The device is worn by the patient throughout the day and attached to the head by electrodes which creates a low intensity, alternating electric field within the tumor that exerts physical forces on electrically charged cellular components, preventing the normal mitotic process and causing cancer cell death prior to division.

Guidelines from the National Comprehensive Cancer Network (NCCN) on central nervous system cancers, recommend alternating electrical fields therapy as a treatment option for newly diagnosed glioblastoma for patients with good performance status and either methylated or unmethylated/indeterminate MGMT promoter status,in conjunction with standard brain radiation therapy plus concurrent temozolomide and adjuvant temozolomide.(category 1 recommendation-based on high- level evidence.) (1,2) For recurrent glioblastoma, NCCN gives alternating electrical field therapy a 2B rating (consensus based upon lower-level evidence.)

Hayes conducted a review of the available literature on TTF, noting that overall the body of evidence was of fair to very poor quality, although it was consistently positive. Hayes found the evidence to be stronger for the use of TTF for recurrent disease as opposed to newly diagnosed disease, as there were more supportive studies for recurrent disease at the time of publication (2 vs. 6). Out of the 10 studies they reviewed, pertaining to the use of TTF in patients with GBM and select other cancers, two were of fair quality, and the other eight ranged from poor quality to very poor quality. The two fair quality trials were those conducted by Stupp et al. in 20125 and 20154, although these were noted to have limitations such as lack of a sham intervention and significant loss to follow up (22% and 20%, respectively). (3)

Medical Policy

The FDA based its approval of the newly diagnosed glioblastoma indication of the Optune device on results from a 2015 clinical trial by Stupp et al.5. (4) The EF-14 trial included 695 patients newly diagnosed with GB and compared those who used Optune with temozolomide to those receiving temozolomide alone. Patients who used the device along with temozolomide lived, on average, about seven months with no disease progression compared to four months for those who had the drug alone. The Optune plus temozolomide group survived for an average of 19.4 months after starting treatment compared to 16.6 months for those who were treated with only temozolomide5. One critique of this study is that the study was terminated at the pre-planned intermediate analysis due to success of the TTF treatment. With the newly diagnosed glioblastoma indication, Optune can be used for GBM before the disease progresses. For newly diagnosed GBM, Optune is not intended to be used as a substitute for standard treatments, but rather as an adjunct therapy, and should not be used without a physician's supervision.

DEFINITIONS

1. **Authorization:** A decision by Brand New Day/Central Health Medicare Plan that a health care service, treatment plan, prescription drug or durable medical equipment is medically necessary or meets other member contract terms. Sometimes called prior authorization, prior approval or precertification. Brand New Day/Central Health Medicare Plan requires preauthorization for certain services before a member receives them, except in an emergency. Authorization is not a promise that Brand New Day/Central Health Medicare Plan will cover the cost.

2. **Tumor Treating Fields (TTF) therapy**: A noninvasive technology intended to treat glioblastoma at home using electrical fields.

3. **Karnofsky Performance Status (KPS) scale:** A scale that 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.

4. Temozolomide: Chemotherapy drug used as a first-line treatment for glioblastoma.

CODING

The codes listed below are for reference purposes. This list does not imply whether the code is covered or not covered. The benefit document should be referenced for coverage determination. This list of applicable codes may not be all-inclusive.

CPT CODE	DESCRIPTION
N/A	

HCPCS CODE	DESCRIPTION
A4555	Electrode/transducer for use with electrical stimulation device used for cancer treatment, replacement only
E0766	Electrical stimulation device used for cancer treatment, includes all accessories, any type

Medical Policy

ICD 10 CODE	DESCRIPTION
C71.0-C71.9	Malignant Neoplasm of the brain

EVIDENCE BASED REFERENCES

1. National Comprehensive Cancer Network (NCCN). Central nervous system cancers. NCCN Clinical Practice Guidelines in Oncology. Version 3.2019.
2. U.S. FDA. Optune Approval (Formerly the NovoTTF-100A System). October 5, 2015. Available at: http://www.accessdata.fda.gov/cdrh_docs/pdf10/P100034S013a.pdf
3. Hayes Health Technology Assessment. Tumor Treating Fields (Optune). Dec 27, 2019.
4. UpToDate. Initial treatment and prognosis of newly diagnosed glioblastoma in adults. Alternating Electric Fields Nov 27, 2019

POLICY HISTORY

This policy has been approved by the approval body listed below or has received other necessary approval pursuant to Brand New Day/Central Health Medicare Plan policies on clinical criteria and policy development.

Approval Body	Utilization Management Committee		
Version History	**Approval Date**	**Effective Date**	**Action**
V1	09-24-2020	09-24-2020	New Policy
V2	12-20-2020	12-20-2020	Updated to reflect new lines of business
V3	09-23-2021	09-23-2021	Annual review
V4	09-28-2022	09-28-2022	Annual review
V5	09-28-2022	03-01-2023	Adopted by MA UM Committee (no policy revisions made)
V6		01-01-2024	Updated to Brand New Day/Central Health Medicare Plan (no policy revisions made)