Subject: Durable Medical Equipment: Alternating Electromagnetic Field Therapy for Glioblastoma

Medical Policy #: 34.0 **Original Effective Date:** 05/22/2019

Status: Reviewed **Last Review Date:** 02/07/2024

Disclaimer

Refer to the member's specific benefit plan and Schedule of Benefits to determine coverage. This may not be a benefit on all plans or the plan may have broader or more limited benefits than those listed in this Medical Policy.

Description

Purpose of Technology: Optune™ (previously known as NovoTTF-100A System™), is a wearable, non-invasive device that generates Tumor Treating Fields (TTFields), an effective anti-mitotic therapy for glioblastoma. The system delivers intermediate frequency, alternating electric fields to the supratentorial brain. Patient therapy is personalized by configuring transducer array layout placement on the scalp to the tumor site using MRI measurements and the NovoTAL System. Transducer array layout mapping optimizes therapy by maximizing electric field intensity to the tumor site. Novocure has been approved for use in patients with recurrent glioblastoma multiforme (GBM).

Preparation: Transducer arrays are applied to the shaved scalp. The arrays are worn continuously for 3 to 4 days before removal for hygienic care of the scalp, re-shaving of hair, and reapplication with new a set of arrays. Patients and/or caregivers are trained to apply and remove the transducer arrays and clean, shave, and prepare the scalp for reapplication.

Alternating Electric Magnetic Field Therapy is a device that generate electromagnetic fields utilized in the treatment of cancer. The electromagnetic energy generated is transmitted to the body by means of surface electrodes or transducers.

Tumor treatment field therapy (TTFT) devices are covered under the Durable Medical Equipment benefit (E0766).

Coverage Determination

Prior Authorization is required. Logon to Pres Online to submit a request: https://ds.phs.org/preslogin/index.jsp

Alternating electric field therapy is only an option for patients with supratentorial disease. Tumor treatment field therapy (TTFT) device is used for both **recurrent** glioblastoma (GBM) and **newly** diagnosed glioblastoma. The use of TTFT for any other tumor(s) will be denied as not reasonable and necessary.

I. Recurrent Glioblastoma

TTTF for recurrent Glioblastoma is a covered benefit for **Medicaid, Commercial and Medicare** members:

PHP covers tumor treatment field therapy (TTFT) for the diagnosis or treatment of *recurrent Glioblastoma*. It must be reasonable or medically necessary, and when **all** of the following criteria are met for recurrent Glioblastoma:

- Glioblastoma, post-surgery and radiotherapy;
- Adult (22 years of age and older);
  and
- Willing to wear the device for at least 18 hours per day
  and
- Train either member or caregiver to apply the device.

II. Newly Diagnosed Glioblastoma

TTFT for newly diagnosed Glioblastoma is a covered benefit for **Medicare, Medicaid and Commercial** members:

PHP follows CMS LCD (L34823), Tumor Treatment Field Therapy (TTFT).

TTFT for *newly diagnosed* Glioblastoma is considered medically necessary when the criteria are met as indicated in the LCD guidelines mentioned above.

Continued Treatment of newly diagnosed GBM beyond three months of therapy:

For continued coverage of TTFT beyond 3 months of therapy, provider must re-evaluate member no sooner than the 60th day, but no later than the 91st day after initiating therapy. Extension beyond 91st day may be allowed with good reason to continue coverage of TTFT. Documentation must support the need to continue TTFT; the adherence to the use of TTFT for an average of 18 hours per day, during the face-to-face clinical re-evaluation.

Documentation

PHP is following CMS Policy Article for the documentation requirements. Please see (A52711) for durable medical equipment general documentation requirements.

Coding

The coding listed in this medical policy is for reference only. Covered and non-covered codes are within this list.

Code E0766 is in the frequent and substantial service payment category. Items included in this payment category are reimbursed a single monthly fee schedule amount for the device and all related supplies and accessories. Separate billing of supplies and/or accessories will be denied as unbundling.

Tumor Treatment Field Therapy (TTFT)-HCPCS Codes

HCPCS Codes	Product Name	Description
E0766	NOVO TTF-100A Electric Field Generator and System Components.	Electrical stimulation device used for cancer treatment, **includes all accessories**, any type **NOTE**: This code is inclusive of all associated supplies necessary for the effective use of code E0766 including, but not limited to, transducers/surface electrodes, lead wires, adhesive patches, connectors, conductive gel and skin preps.

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

ICD-10 Diagnosis Codes

ICD10 Codes	Description (* represents a range of codes)
C71*****	Malignant neoplasm of brain (grade IV astrocytoma).
C79.31	Secondary malignant neoplasm of brain.

Reviewed by / Approval Signatures

Population Health & Clinical Quality Committee: Gray Clarke MD
VP Associate Chief Medical Officer: Clinton White MD
Medical Director: Ana Maria Rael MD
Senior Medical Director: Jimmy Romero MD
Date Approved: 02/07/2024

References

1. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology™ (NCCN Guidelines®), Central Nervous System Cancers, Version Version 1.2023 — March 24, 2023 , Accessed 12/14/2023
2. NovoTTF-100A System (Tumor Treating Fields) transducer array layout planning for glioblastoma: a NovoTAL system user study. (Chaudhry et al., 2015), World Journal of Surgical Oncology [Cited 11/30/2022]
3. CMS, Tumor Treatment Field Therapy (TTFT), Policy Article (A52711), Revision date 01/01/2020, R7. Accessed 12/14/2023.
4. CGS DME, Tumor Treatment Field Therapy (TTFT) (L34823), Revision date: 01/01/2020, Revision number R8. Accessed 12/14/2023
5. MCG, Ambulatory Care, 27th Edition Alternating Electric Field Therapy, ACG: A-0930. Last Update 9/21/2023. [Cited Sept-2023]
6. Hayes, Tumor Treating Field (Optune) for Treatment of Glioblastoma, Health Tech Assessment Dec 27, 2019, Annual review Jan 05-2023. [Cited 12/14/2023]
7. Aetna, Electric Tumor Treatment Fields, # 0827, Next Review: 09-08-2022. [Cited 12/15/2023]

8. Humana, Electric Tumor Treatment Fields, Review Date: 02/02/2023 Policy Number: HUM-0517-013,. [Cited 12/13/203]
9. UnitedHealthcare® Commercial Medical Policy, Electric Tumor Treatment Field Therapy, Effective Date: November 1, 2023, Policy Number: 2023T0582L. [Cited 12/13/2023]
10. FDA, Novocure LTD's NovoTTf-100A Treatment Kit refer to the following website for the initial Premarket Approval information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P100034. [Accessed 12/14/2023]

Publication History

07/31/19 Reviewed and approved by TAC on 01/23/2019, PA required and coverage only for recurrent Glioblastoma.

11/20/19 Reviewed and approved by TAC on **10/16/2019**, to include criteria for newly diagnosed supratentorial glioblastoma for Medicare, Medicaid and Commercial, and recurrent Glioblastoma to exclude Medicare

01/27/21 Annual review. Reviewed by PHP Medical Policy Committee on 12/18/2020.

- Correction was made to TAC decision on 10/16/2019. The TAC committee recommended coverage for all product line for both "newly diagnosed glioblastoma" and "recurrent supratentorial GBM" with prior authorization. Due to the correction the following has changed in the policy.
- **Recurrent glioblastoma** has changed to now include Medicare (even though we are aware Medicare does not allow coverage per LCD L34823). Will continue to follow the homegrown criteria previously outlined.
- **Newly diagnosed glioblastoma** has changed to now follow MCG LCD: L34823R008 (MCR) for all LOB. The criteria has been removed.
- Will continue PA for CPT code: E0766, A4555 for all LOB.
- Add ICD-10 (C79.31) for Secondary malignant neoplasm of the brain.

01/26/22 Annual review. Reviewed by PHP Medical Policy Committee on 12/10/2021. No change. Continue coverage for newly diagnosed and recurrent supratentorial GBM for all lines of business. Continue PA requirement for E0766 and A4555. Possible development of a contract for Optune device.

01/25/23 Annual review. Reviewed by PHP Medical Policy Committee on 11/30/2022. Continue coverage for newly diagnosed and recurrent supratentorial GBM along with treatment of GBM after 3 months for all lines of business. Continue PA requirement for E0766 and A4555.

02/07/24 Annual review. Reviewed by PHP Medical Policy Committee on 12/15/2023. Continue coverage for newly diagnosed and recurrent supratentorial GBM along with treatment of GBM after 3 months for all lines of business. Continue PA requirement for E0766 and A4555.

This Medical Policy is intended to represent clinical guidelines describing medical appropriateness and is developed to assist Presbyterian Health Plan and Presbyterian Insurance Company, Inc. (Presbyterian) Health Services staff and Presbyterian medical directors in determination of coverage. The Medical Policy is not a treatment guide and should not be used as such.

For those instances where a member does not meet the criteria described in these guidelines, additional information supporting medical necessity is welcome and may be utilized by the medical director in reviewing the case. Please note that all Presbyterian Medical Policies are available online at: ***Click here for Medical Policies***

Web links:
At any time during your visit to this policy and find the source material web links has been updated, retired or superseded, PHP is not responsible for the continued viability of websites listed in this policy.

When PHP follows a particular guideline such as LCDs, NCDs, MCG, NCCN etc., for the purposes of determining coverage; it is expected providers maintain or have access to appropriate documentation when requested to support coverage. See the References section to view the source materials used to develop this resource document.