

Medical Coverage Policy

Policy Number – MP21-015E

Original review date – 12/13/2021

Effective date – 08/20/2024

Electric tumor treatment fields

Definition

Glioblastoma multiforme (also known as Grade IV astrocytoma) is the most common malignant brain tumor in adults, commonly treated with surgery, followed by radiation therapy and adjuvant chemotherapy. Even with maximal therapy, glioblastoma has a high rate of recurrence and poor overall survival for most patients. Novel therapies with reduced toxicity are needed for these patients.

The Optune device is an FDA approved wearable device that generates low intensity alternating electric fields of intermediate frequency. These alternating electric fields, called tumor treating fields, disrupt rapid cell division and slow the progression of cancer. The mechanism of action is by interference with the formation of the mitotic spindle and microtubules, as well as physical destruction of cells during cleavage.

The Optune system consists of an electrical field generator, transducer arrays, power source, and a carrying case. Transducer pads are applied to the shaved scalp, directly above the tumor. These are replaced once or twice per week. The device is light (3-6 pounds), and is designed to be worn for at least 18 hours a day for the duration of the treatment. Treatment parameters are preset and no electrical output adjustments can be made by the patient.

Policy statement

Disclaimer: This policy is applicable to TRICARE Prime and Select beneficiaries and may not apply to Active Duty Service Members (ADSM) under Supplemental Health Care Program (SHCP) or TRICARE Prime Remote (TPR) in accordance with TRICARE Operations Manual (TOM) Chapter 17, Section 3. Please review TOM Chapter 17, Section 3, Paragraph 2.0 onwards, regarding SHCP coverage and any TRICARE-specific exclusions included in this coverage policy to accurately determine the benefit for ADSMs.

.

Electric Tumor Treatment Fields (ETTF) therapy may be covered initially for 6 months if ALL the following criteria are met:

- I. Age 22 years or older
- II. Karnofsky Performance Scale status score greater than or equal to 60
- III. One of the following diagnoses:
 - a. Recurrent supratentorial glioblastoma multiforme, confirmed by histology or radiology. ETTF to be used as a monotherapy after surgical and radiation options have been exhausted
 - b. Other indications such as newly diagnosed supratentorial glioblastoma multiforme may be considered for coverage per medical director review
- IV. No deep brain, spinal cord, or implanted nerve stimulators

- V. No cardiac pacemaker or implantable defibrillator
- VI. No metal within brain (e.g., bullet fragment, aneurysm clip)
- VII. No programmable ventriculoperitoneal shunt
- VIII. No skull defects such as missing section of bone

Continued coverage beyond initial 6 months may be approved if the following conditions are met:

- I. Documentation of use of device for at least 18 hours a day
- II. Karnofsky Performance Scale status score greater than or equal to 60
- III. No disease progression, which is defined as either tumor growth greater than 25% of contrast enhanced lesions or the appearance of new lesions in the brain

Coding information

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

TRICARE Policy Manual Chapter 1, section 3.1

2.13 Effective September 1, 2012, the NovoTTF-100A system (HCPCS A4555 and E0766) may be cost-shared for the treatment of adult patients (22 years of age or older) with recurrent glioblastoma after surgical and radiation options have been exhausted.

References

1. TRICARE Policy Manual Chapter 1, Section 3.1 [TRICARE Manuals - Manual Information \(health.mil\)](#)
2. MCG Health. Alternating Electric Field Therapy. Ambulatory Care. 27th edition. ACG: A-0930 (AC). Last reviewed: 09/21/2023
3. Uptodate Inc. Initial treatment and prognosis of IDH-wildtype glioblastoma in adults. Last reviewed August 7, 2024
4. Uptodate Inc. Management of glioblastoma in older adults. Last reviewed August 15, 2023
5. Uptodate Inc. Management of recurrent high-grade gliomas. Last reviewed July 11, 2024
6. National Comprehensive Cancer Care Network (NCCN). Central Nervous System Cancers. Version 2.2024. – July 25, 2024
7. Hayes Inc. Tumor Treating Fields (Optune) for Treatment of Glioblastoma. Updated: 01/05/2023
8. Centers for Medicare and Medicaid Services. Local Coverage Determination (LCD) L34823. Tumor Treatment Field Therapy. Effective Date 01/01/2020
9. Centers for Medicare and Medicaid Services. Local Coverage Article. A52711 Tumor Treatment Field Therapy – Policy Article. Effective Date 01/01/2020

Revision History

August 2024: Updated references and coding

August 2023:

- Added criteria for continued coverage beyond initial 6 months
- Updated references

Approved by:



Joseph F. McKeon, MD, MPH

Chief Medical Officer

Date of approval: 8/20/2024