

Subject: Tumor Treating Fields

Background: Glioblastomas (grade IV astrocytomas) are one of the most common types of primary malignant brain tumors in adults. These tumors develop from glial cells in the brain and are usually highly malignant (cancerous) because the cells reproduce quickly, and they are supported by a large network of blood vessels. The overall prognosis is poor, even with the best standard of care. Currently, the standard of care for glioblastoma multiforme (GBM) includes debulking surgery, combination treatment with radiotherapy and Temozolomide (TMZ) chemotherapy, and adjuvant chemotherapy with TMZ. With optimal treatment, the median survival time is approximately 10 to 14 months. Only approximately one third of patients survive for one year following diagnosis of GBM, and fewer than 5% live beyond 5 years. Virtually all patients with newly diagnosed GBM relapse despite best available treatment. Patients with recurrent GBM have a median survival time of five to seven months.

Tumor treating fields (TTF) therapy is a novel treatment which utilizes mild electrical field pulses to inhibit cell proliferation and leads to programmed cell death in the treatment of glioblastomas. Tumor treating fields (TTF) therapy is administered via a portable medical device that generates low-intensity alternating electric fields, called tumor treating fields. TTF aims to treat GBM by disrupting the rapid cell division exhibited by malignant cells

Authorization:

Prior authorization is required for electric tumor treating field devices provided to members enrolled in commercial (HMO, POS, PPO) products.

Policy and Coverage Criteria:

The Plan considers the use of U.S. Food and Drug Administration (FDA)-approved tumor treating fields (TTF) devices (e.g. Optune[®]) as reasonable and medically necessary for histologically confirmed glioblastoma multiforme when documentation confirms ALL the following:

- Newly diagnosed supratentorial glioblastoma following both debulking surgery and radiation therapy with concomitant chemotherapy and ALL of the following are met:
 - TTF is in combination with temozolomide (TMZ); AND
 - Member is 22 years of age or older; AND
 - Member has the ability to use the device for an average of 18 hours each day; AND
 - Member has Karnofsky score > 70 or Eastern Cooperative Oncology Group (ECOG) performance status 0-1.
- TTF as monotherapy in member with histologically or radiologically confirmed recurrent glioblastoma (GBM) in the supratentorial region of the brain after receiving chemotherapy and ALL the following are met:
 - Surgical and radiation options have been exhausted; AND
 - Member is 22 years of age or older; AND

- Member has the ability to use the device for an average of 18 hours each day.

NOTE: Authorization will be in three-month increments.

Exclusions:

The use of tumor treating field (TTF) devices as experimental/investigational for all other indications.

Guidelines:

Eastern Cooperative Oncology Group (ECOG) performance status

Grade	ECOG Performance Status
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work
2	Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours
3	Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours
4	Completely disabled; cannot carry on any selfcare; totally confined to bed or chair
5	Dead

Karnofsky Performance Status Scale

Condition	Value (%)	Level of Functional Capacity
Able to carry on normal activity and to work; no special care needed	100%	No complaints; no evidence of disease
	90%	Able to carry on normal activity; minor signs or symptoms of disease
	80%	Normal activity with effort; some signs or symptoms of disease
Unable to work; able to live at home and care for most personal needs; varying amount of assistance needed	70%	Cares for self; unable to carry on normal activity or to do active work
	60%	Requires occasional assistance but is able to care for most personal needs
	50%	Requires considerable assistance and frequent medical care
Unable to care for self; requires equivalent of institutional or hospital care; diseases may be progressing rapidly	40%	Disabled; requires special care and assistance
	30%	Severely disabled; hospital admission indicated although death not imminent
	20%	Very sick; hospital admission necessary; active supportive treatment necessary

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	10%	Moribund; fatal processes progressing rapidly
	0%	Dead

Coding:

Codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible.

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

Billing Guidelines:

Member’s medical records must document that services are medically necessary for the care provided. Harvard Pilgrim Health Care maintains the right to audit the services provided to our members, regardless of the participation status of the provider. All documentation must be available to HPHC upon request. Failure to produce the requested information may result in denial or retraction of payment.

References:

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3. Local Coverage Determination (LCD): Tumor Treatment Field Therapy (TTFT) (L34823). CMS.gov. 2020. Accessed October 13, 2021
4. Louis D, Perry A, Reifenberger G et al. The 2016 World Health Organization Classification of Tumors of the Central Nervous System: a summary. - PubMed - NCBI. 2018. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/27157931>. Accessed October 13, 2021
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7. Optune Treatment Kit (Novocure, Ltd.) for Treating Newly Diagnosed Glioblastoma. ECRI.org/login [via subscription only]. Accessed October 13, 2021.
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10. Silginer M, Weller M, Stupp R, Roth P. Biological activity of tumor-treating fields in preclinical glioma models. Cell Death Dis 2017;8:e2753; doi:10.1038/cddis.2017.171.
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Summary of Changes:

Date	Changes
11/21	Annual review; criteria and coding updated for integration purposes with Tufts Health Plan (THP)
10/20	Annual review; criteria, supporting information and guidelines updated
10/19	Annual review; minor criteria updates
11/18	Policy criteria updated; prior authorization updated
9/18	Policy coverage criteria updated
4/17	Removed ICD-9 references

Approved by Medical Policy Committee: 11/02/21

Approved by Clinical Policy Operational Committee: 10/16; 4/17; 11/18; 10/19; 11/20; 12/21

Policy Effective Date: 03/01/21

Initiated: 10/16

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