Introduction

Tumor treating fields (TTF) is a new treatment being studied for use in certain cancers. The therapy consists of low-level electrical currents that arise from small insulated electrodes placed on the skin surface. TTF is believed to cause cell death during a later stage of development. Currently this therapy is covered as one treatment option for people who have a form of brain cancer called glioblastoma multiforme. People wear a helmet with small electrodes attached to the scalp for at least 18 hours per day during TTF therapy. This treatment requires pre-approval by the plan, and this policy describes when this treatment is covered. TTF is considered investigational for other types of cancer (therefore not covered), as there is not yet enough scientific data that shows it works for other diagnoses.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
<table>
<thead>
<tr>
<th>Condition</th>
<th>Medical Necessity</th>
</tr>
</thead>
</table>
| Glioblastoma-adjuvant therapy   | **Tumor treating fields (TTF) therapy to treat newly diagnosed glioblastoma is considered medically necessary when ALL of the following are met:**  
  - The patient is ≥ 18 years of age  
  - The tumor is in the supratentorial region of the brain (the cerebrum)  
  - The patient has a Karnofsky Performance Status score ≥ 70% (see table below)  
  - The patient has completed initial treatment with ALL of the following:   
    - Surgery (resection, debulking, or biopsy)  
    - Radiation therapy  
    - Chemotherapy (if applicable)  
  AND  
  - The patient is receiving standard maintenance therapy with Temodar® (temozolomide) |

<table>
<thead>
<tr>
<th>Condition</th>
<th>Investigational</th>
</tr>
</thead>
</table>
| All other conditions            | **Tumor treating fields (TTF) therapy is considered investigational in all other conditions, including but not limited to the following situations:**  
  - As an adjunct to standard medical therapy (eg, Avastin® [bevacizumab], chemotherapy) for progressive or recurrent glioblastoma  
  - As an alternative to standard medical therapy (eg, Avastin® [bevacizumab], chemotherapy) for progressive or recurrent glioblastoma multiforme  
  - As an adjunct to standard medical therapy (pemetrexed and platinum-based chemotherapy) for patients with malignant pleural mesothelioma  
  - For brain metastases  
  - For cancer in areas other than the brain |
**Documentation Requirements**

The patient’s medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:

- Location of the brain tumor
- Karnofsky Performance Status score ≥ 70%
- Documentation that member has completed initial treatment with **ALL** of the following:
  - Surgery (resection, debulking, or biopsy)
  - Radiation therapy
  - Chemotherapy (if applicable)

**AND**

- Documentation that the patient is receiving standard maintenance therapy with Temodar® (temozolomide)

**Coding**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A4555</td>
<td>Electrode/transducer for use with electrical stimulation device used for cancer treatment, replacement only</td>
</tr>
<tr>
<td>E0766</td>
<td>Electrical stimulation device used for cancer treatment, includes all accessories, any type</td>
</tr>
</tbody>
</table>

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

**Related Information**

Progression was defined in the study trial as tumor growth > 25% compared with the smallest tumor area measured or the appearance of 1 or more new tumors in the brain that are diagnosed radiologically as glioblastoma.

Continuation of treatment is allowed until documented progression or recurrence of the tumor. MRI report is required every 6 months to demonstrate there is no progression or recurrence of the tumor.
The FDA label includes the following:

- Patients should use Optune for at least 18 hours a day to get the best response to treatment.
- Patients should finish at least 4 full weeks of therapy to get the best response to treatment. Stopping treatment before 4 weeks lowers the chances of a response to treatment.

### Karnofsky Performance Status Scale Definitions Rating (%) Criteria

<table>
<thead>
<tr>
<th>Ability</th>
<th>Rating (%)</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Able to carry on normal activity and to work; no special care needed</td>
<td>100</td>
<td>Normal no complaints; no evidence of disease</td>
</tr>
<tr>
<td>90</td>
<td>Able to carry on normal activity; minor signs or symptoms of disease</td>
<td></td>
</tr>
<tr>
<td>80</td>
<td>Normal activity with effort; some signs or symptoms of disease</td>
<td></td>
</tr>
<tr>
<td>Unable to work; able to live at home and care for most personal needs; varying amount of assistance needed</td>
<td>70</td>
<td>Cares for self; unable to carry on normal activity or to do active work</td>
</tr>
<tr>
<td>60</td>
<td>Requires occasional assistance, but is able to care for most of his personal needs</td>
<td></td>
</tr>
<tr>
<td>50</td>
<td>Requires considerable assistance and frequent medical care</td>
<td></td>
</tr>
<tr>
<td>Unable to care for self; requires equivalent of institutional or hospital care; disease may be progressing rapidly</td>
<td>40</td>
<td>Disabled; requires special care and assistance</td>
</tr>
<tr>
<td>30</td>
<td>Severely disabled; hospital admission is indicated although death not imminent</td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>Very sick; hospital admission necessary; active</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Moribund; fatal processes progressing rapidly</td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>Dead</td>
<td></td>
</tr>
</tbody>
</table>


---

### Evidence Review

### Description

Tumor treating fields (TTF) therapy is a noninvasive technology intended to treat glioblastoma and malignant pleural mesothelioma on an outpatient basis and at home using electrical fields. Glioblastoma multiforme (GBM) is the most common and deadly malignant brain tumor. It has a very poor prognosis and is associated with low quality of life during treatment. Malignant
pleural mesothelioma is an aggressive tumor with few treatment options that is associated with significant morbidity and mortality.

Background

**Glioblastoma Multiforme**

Glioblastomas, also known as glioblastoma multiforme (GBM), are the most common form of malignant primary brain tumor in adults.¹ GBMs are grade IV astrocytomas, a rapidly progressing and deadly type of glial cell tumor that is often resistant to standard medical therapy (eg, bevacizumab, chemotherapy). Together, anaplastic astrocytomas and glioblastomas comprise approximately 38% of all brain and central nervous system tumors.¹ The peak incidence for GBM occurs between the ages of 45 and 70 years, with a median age at diagnosis of 64 years. Glioblastomas have the lowest survival rate of any central nervous system tumor; in one report, about a third of patients survived to 1 year, and the 5-year survival rate was around 5%.²

**Treatment of Newly Diagnosed GBM**

The primary treatment for patients newly diagnosed with GBM is to resect the tumor to confirm a diagnosis while debulking the tumor to relieve symptoms of increased intracranial pressure or compression. If total resection is not feasible, subtotal resection and open biopsy are options. During surgery, some patients may undergo implantation of the tumor cavity with a carmustine (bis-chloroethyl nitrosourea) (Gliadel Wafer®) impregnated wafer. Due to the poor efficacy of local treatment, postsurgical treatment with adjuvant radiotherapy, chemotherapy (typically temozolomide), or a combination of these 2 therapies is recommended. After adjuvant therapy, patients may undergo maintenance therapy with temozolomide. Maintenance temozolomide is given for 5 days of every 28-day cycle for 6 cycles. Response and overall survival rates with temozolomide are higher in patients who have O⁶-methylguanine-DNA methyltransferase (MGMT) gene promoter methylation.

Prognostic factors for therapy success are age, histology, performance status or physical condition of the patient, and extent of resection. National Comprehensive Cancer Network recommendations include patient age and Karnofsky Performance Status score as important determinants of postsurgical treatment choice.³ For patients with good performance status, the most aggressive treatment (standard radiotherapy [RT] plus temozolomide) is recommended. For patients with poor performance status, only single treatment cycles or even palliative or
supportive care are recommended. Hypofractionated RT is indicated for patients with poor performance status because it is better tolerated, and more patients are able to complete RT. Treatment of GBM is rarely curative, and tumors will recur essentially in all patients.

**Treatment of Recurrent GBM**

When disease recurs, additional debulking surgery may be used if the recurrence is localized. Due to radiation tolerances, re-radiation options for patients with recurrent GBM who have previously received initial external-beam radiotherapy are limited. There is no standard adjunctive treatment for recurrent GBM. Treatment options for recurrent disease include various forms of systemic medications such as the antivascular endothelial growth factor drug bevacizumab, alkylating agents such as nitrosoureas (eg, lomustine, carmustine), or retreatment with temozolomide. Medical therapy is associated with side effects that include hematologic toxicity, headache, loss of appetite, nausea, vomiting, and fatigue. Response rates in recurrent disease are less than 10%, and the progression-free survival rate at 6 months is less than 20%. There is a need for new treatments that can improve survival in patients with recurrent GBM or reduce the side effects of treatment while retaining survival benefits.

**Malignant Pleural Mesothelioma**

Malignant pleural mesothelioma (MPM) is an aggressive tumor that is associated with significant morbidity and mortality. It is associated with asbestos exposure and has a latency period of about 40 years after asbestos exposure. Recommendations for treatment are mainly chemotherapy as first line with pemetrexed (Alimta®) plus platinum. Surgical cytoreduction is also recommended in selected patients with early-stage disease. Adjuvant radiation can be offered for patients who have resection of intervention tracts found to be histologically positive or for palliation of symptomatic patients.

Optune (formerly NovoTTF-100A System) is the only legally marketed TTF delivery system available in the United States. The portable, battery-powered device is carried in a backpack or shoulder pack while carrying out activities of daily living. For the treatment of glioblastoma, four disposable transducer arrays with insulated electrodes are applied to the patient’s shaved head. The transducer array layout is typically determined using specialized software. The patient’s scalp is re-shaved and the transducer arrays replaced twice a week by the patient, caregiver, or device technician. The device is worn for up to 24 hours a day for the duration of treatment, except for brief periods for personal hygiene and two to three days at the end of each month.
The minimum daily treatment is 18 hours. The minimum duration of treatment is one month, with the continuation of treatment available until recurrence.

Summary of Evidence

For individuals who have newly diagnosed GBM on maintenance therapy after initial treatment who receive TTF therapy as an adjunct to standard maintenance therapy, the evidence includes an RCT. Relevant outcomes include overall survival, disease-specific survival, symptoms, functional outcomes, quality of life, and treatment-related morbidity. The EF-14 trial found a significant increase of 2.7 months in progression-free survival and an increase of 4.9 months in overall survival with the addition of TTF therapy to standard maintenance therapy (ie, temozolomide) in patients with newly diagnosed GBM. Although patients were not blinded to treatment assignment, progression-free survival was assessed by blinded evaluators, and the placebo effects on the objective measure of overall survival are expected to be minimal. This technology represents a clinically significant option in the treatment of patients with GBM, for whom options are limited. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have progressive or recurrent GBM who receive TTF therapy as an adjunct or alternative to standard medical therapy, the evidence includes an RCT and nonrandomized comparative studies. Relevant outcomes are overall survival, disease-specific survival, quality of life, and treatment-related morbidity. The single RCT evaluating TTF therapy for recurrent GBM did not show superiority of TTF therapy for the primary outcome (overall survival) compared with physicians’ choice chemotherapy. Because no serious adverse effects have been identified with TTF therapy, this raises the possibility that treatment with TTF might reduce the toxicity associated with treatment for recurrent GBM. A reduction in chemotherapy-associated toxicity without loss of efficacy would be considered a net health benefit. However, this RCT is not sufficient to permit conclusions on the efficacy of the device. Because the trial was not designed as a noninferiority trial, no inferences of noninferiority compared with chemotherapy can be made. Also, quality of life assessment was measured in an insufficient number of patients to reach firm conclusions on differences in quality of life between TTF therapy and medical treatment. The highest quality study of TTF combined with medical treatment for recurrent GBM is a post hoc analysis of the EF-14 trial. A high quality, prospective RCT is needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have unresectable, locally advanced or metastatic, malignant pleural mesothelioma who receive TTF therapy as an adjunct to standard maintenance therapy, the evidence includes one single-arm observational study conducted in 80 patients. Relevant
outcomes include overall survival, disease-specific survival, symptoms, functional outcomes, quality of life, and treatment-related morbidity. The study has not been published but is described in the FDA Summary associated with its Humanitarian Device Exemption designation. In patients who received TTF therapy in combination with pemetrexed (Alimta®) and cisplatin or carboplatin, median overall survival was 18.2 months (95% CI 12.3 to 25.8 months). Because there was no comparison group, it is not possible to make conclusions about the effectiveness of the intervention compared to medical therapy alone. The evidence is insufficient to determine that the technology results in a meaningful improvement in the net health outcome.

**Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this review are listed in **Table 1**. Of particular note are the phase 3 trials evaluating TTF therapy in non-small-cell lung cancer and pancreatic cancer. TTF therapy is an active area of research for mechanisms underlying its effects on cancer cells.

**Table 1. Summary of Key Trials**

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT03940196a</td>
<td>ENGOT-ov50 / GOG-3029 / INNOVATE-3: Pivotal, Randomized, Open-label Study of Tumor Treating Fields (TT Fields, 200kHz) Concomitant With Weekly Paclitaxel for the Treatment of Platinum-resistant Ovarian Cancer (PROC)</td>
<td>540</td>
<td>Dec 2024</td>
</tr>
<tr>
<td>NCT01971281a</td>
<td>A Phase II Study of TTFields (150 kHz) Concomitant With Gemcitabine and TTFields Concomitant With Gemcitabine Plus Nab-paclitaxel for Front-line Therapy of Advanced Pancreatic Adenocarcinoma</td>
<td>40</td>
<td>Dec 2017 (ongoing)</td>
</tr>
<tr>
<td>NCT01894061a</td>
<td>A Prospective Phase II Trial of NovoTTF-100A With Bevacizumab (Avastin) in Patients With Recurrent Glioblastoma</td>
<td>40</td>
<td>Dec 2019</td>
</tr>
<tr>
<td>NCT02663271a</td>
<td>A Phase 2, Multi-center, Single Arm, Histologically Controlled Study Testing the Combination of TTFields and Pulsed Bevacizumab Treatment in Patients With Bevacizumab-refractory Recurrent Glioblastoma</td>
<td>18</td>
<td>Mar 2020</td>
</tr>
<tr>
<td>NCT No.</td>
<td>Trial Name</td>
<td>Planned Enrollment</td>
<td>Completion Date</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>--------------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>NCT02831959a</td>
<td>Pivotal, Open-label, Randomized Study of Radiosurgery With or Without Tumor Treating Fields (TTFields) (150kHz) for 1-10 Brain Metastases From Non-small Cell Lung Cancer (NSCLC) (METIS)</td>
<td>270</td>
<td>Jul 2019</td>
</tr>
<tr>
<td>NCT02973789a</td>
<td>LUNAR: Pivotal, Randomized, Open-label Study of Tumor Treating Fields (TTFields) Concurrent With Standard of Care Therapies for Treatment of Stage 4 Non-small Cell Lung Cancer (NSCLC) Following Platinum Failure</td>
<td>534</td>
<td>Dec 2021</td>
</tr>
<tr>
<td>NCT02743078a</td>
<td>Phase II Trial Of Optune® Plus Bevacizumab In Bevacizumab-Refractory Recurrent Glioblastoma</td>
<td>85</td>
<td>Aug 2022</td>
</tr>
<tr>
<td>NCT03377491a</td>
<td>EF-27 Pivotal, Randomized, Open-label Study of Tumor Treating Fields (TTFields, 150kHz) Concomitant With Gemcitabine and Nab-paclitaxel for Front-line Treatment of Locally-advanced Pancreatic Adenocarcinoma (PANOVA-3)</td>
<td>556</td>
<td>Dec 2022</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

a Denotes industry-sponsored or cosponsored trial.

Clinical Input from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from three physician specialty societies (one of which provided six responses and two of which provided one response each) and one academic medical center (total of nine individual responses) while this policy was under review in 2016. There was majority support, but not consensus, for the use of tumor treatment fields therapy as an adjunct to maintenance treatment following initial therapy for glioblastoma multiforme. There was mixed support for the use of tumor treatment fields as an alternative to chemotherapy in advanced or recurrent glioblastoma multiforme.
Practice Guidelines and Position Statements

National Comprehensive Cancer Network

National Comprehensive Cancer Network guidelines on central nervous system cancers (v.1.2018) include recommendations for the treatment of glioblastoma (see Table 2). For the initial treatment of patients with glioblastoma with good performance status and either methylated or unmethylated or indeterminate O\textsuperscript{6}-methylguanine-DNA methyltransferase promotor status, treatment with standard brain radiotherapy plus concurrent temozolomide and adjuvant temozolomide plus alternating electric field therapy is a category 1 recommendation. Alternating electric currents therapy is only an option for patients with supratentorial disease. Consideration of alternating electric field therapy for recurrent glioblastoma is a category 2B recommendation.

Table 2. Guidelines for Adjuvant Treatment of Glioblastoma, by Age and Performance Status

<table>
<thead>
<tr>
<th>Age, y</th>
<th>KPS Score,%</th>
<th>Treatment Options</th>
<th>Category</th>
</tr>
</thead>
</table>
| ≤70    | ≥60         | • Standard RT plus concurrent and adjuvant temozolomide plus TTF  
|        |             | • Standard RT plus concurrent and adjuvant temozolomide          | 1        |
| ≤70    | <60         | • Hypofractionated RT with/without concurrent or adjuvant temozolomide  
|        |             | • Temozolomide  
|        |             | • Palliative/best supportive care                                | 2A       |
| >70    | ≥60         | • Hypofractionated RT plus concurrent and adjuvant temozolomide plus TTF  
|        |             | • Standard RT plus concurrent and adjuvant temozolomide plus TTF  
|        |             | • Temozolomide alone                                             | 1        |
|        |             | • Hypofractionated brain RT alone                                |          |
|        |             | • Temozolomide alone                                             |          |
|        |             | • Palliative/best supportive care                               |          |
| >70    | <60         | • Hypofractionated brain RT alone                                | 2A       |
|        |             | • Temozolomide alone                                             |          |
|        |             | • Palliative/best supportive care                               |          |

KPS: Karnofsky Performance Status; RT: radiotherapy; TTF: tumor treating fields.
Medicare National Coverage

There is no national coverage determination.

Regulatory Status

In April 2011, the NovoTTF-100A™ System (Novocure; assigned the generic name of TTF) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process. The FDA-approved label reads as follows: “The NovoTTF-100A System is intended as a treatment for adult patients (22 years of age or older) with confirmed GBM, following confirmed recurrence in an upper region of the brain (supratentorial) after receiving chemotherapy. The device is intended to be used as a stand-alone treatment and is intended as an alternative to standard medical therapy for recurrent GBM after surgical and radiation options have been exhausted.”

In September 2014, FDA approved Novocure’s request for a product name change from NovoTTF-110A System to Optune®.

In October 2015, FDA expanded the indication for Optune® in combination with temozolomide to include newly diagnosed GBM. The device was granted priority review status in May 2015 because there was no legally marketed alternative device available for the treatment of newly diagnosed GBM, a life-threatening condition. In July 2016, a smaller, lighter version of the Optune® device, called the Optune® System (NovoTTF-200A System), received FDA approval.

The FDA-approved label for newly diagnosed GBM reads as follows: “This device is indicated as treatment for adult patients (22 years of age or older) with histologically-confirmed glioblastoma multiforme (GBM). Optune™ with temozolomide is indicated for the treatment of adult patients with newly diagnosed, supratentorial glioblastoma following maximal debulking surgery and completion of radiation therapy together with concomitant standard of care chemotherapy.”

In May 2019, FDA expanded the indication for the NovoTTFTM-100L System to include "treatment of adult patients with unresectable, locally advanced or metastatic, malignant pleural mesothelioma (MPM) to be used concurrently with pemetrexed and platinum-based chemotherapy. The indication was modified from that granted for the Humanitarian Device Exemption designation to more clearly identify the patient population the device is intended to treat and in which the safety and probable benefit of the device is supported by the available clinical data.”
FDA product code: NZK.

References


## History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/14/13</td>
<td>New Policy. Policy created with literature search through June 3, 2013; considered investigational.</td>
</tr>
<tr>
<td>12/06/13</td>
<td>Update Related Policies. Removed 8.01.31 as it was archived.</td>
</tr>
<tr>
<td>09/01/16</td>
<td>Annual Review, approved August 9, 2016. Changed statement to MN when criteria are met.</td>
</tr>
<tr>
<td>03/30/17</td>
<td>Coding correction; updated code descriptions. Minor formatting update.</td>
</tr>
<tr>
<td>09/01/18</td>
<td>Annual Review, approved August 14, 2018. Policy updated with literature review through April 2018; references 10, and 12-13 added. Title changed from “Tumor Treatment Fields Therapy for Glioblastoma” to “Tumor Treating Fields Therapy”. May be considered medically necessary in conjunction with maintenance temozolomide for patients with newly diagnosed glioblastoma multiforme. Investigational for all other indications.</td>
</tr>
<tr>
<td>10/01/19</td>
<td>Annual Review, approved September 10, 2019. Policy updated with literature review through May 2019. Malignant pleural mesothelioma added to list of conditions for which the therapy is considered investigational.</td>
</tr>
</tbody>
</table>

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  - Information written in other languages

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Email AppealsDepartmentInquiries@Premera.com

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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-5997 (TDD)
Complaint forms are available at

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Italiano (Italian):