Medical Policy

Tumor Treatment Fields Therapy for Glioblastoma

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Policy Number: 514
BCBSA Reference Number: 1.01.29
NCD/LCD: Local Coverage Determination (LCD): Tumor Treatment Field Therapy (TTFT) (L34823)

Related Policies
- Stereotactic Radiosurgery and Stereotactic Body Radiotherapy, #277
- Intraoperative Radiotherapy, #278
- Intracavitary Balloon Catheter Brain Brachytherapy for Malignant Gliomas or Metastasis to the Brain, #602
- Intensity-Modulated Radiotherapy: Central Nervous System Tumors, #910

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Tumor treating fields therapy to treat glioblastoma is considered INVESTIGATIONAL, including but not limited to the following situations:
- As an alternative to standard chemotherapy for patients with advanced or recurrent glioblastoma multiforme
- As an adjunct to standard maintenance therapy in patients with glioblastoma multiforme following initial treatment with surgery and/or radiotherapy.

Medicare HMO BlueSM and Medicare PPO BlueSM Members

Local Coverage Determination (LCD): Tumor Treatment Field Therapy (TTFT) (L34823)

Prior Authorization Information

Pre-service approval is required for all inpatient services for all products. See below for situations where prior authorization may be required or may not be required for outpatient services. Yes indicates that prior authorization is required. No indicates that prior authorization is not required.
Outpatient

<table>
<thead>
<tr>
<th>Service</th>
<th>Coverage Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
<td>This is not a covered service.</td>
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<tr>
<td>Commercial PPO and Indemnity</td>
<td>This is not a covered service.</td>
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<tr>
<td>Medicare HMO BlueSM</td>
<td>This is not a covered service.</td>
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<tr>
<td>Medicare PPO BlueSM</td>
<td>This is not a covered service.</td>
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</table>

CPT Codes / HCPCS Codes / ICD Codes

The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes

There is no specific CPT code for this service.

HCPCS Codes

<table>
<thead>
<tr>
<th>HCPCS codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>E0766</td>
<td>Electrical stimulation device used for cancer treatment, includes all accessories, any type</td>
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Description

**Glioblastome Multiforme**

Glioblastomas, also known as glioblastoma multiforme (GBM), are the most common form of malignant primary brain tumor in adults. They comprise approximately 15% of all brain and central nervous system tumors, and more than 50% of all tumors that arise from glial cells.¹ The peak incidence for GBM occurs between the ages of 45 and 70 years. GBMs are grade IV astrocytomas, the most deadly type of glial cell tumor, and are often resistant to standard chemotherapy.¹ According to the National Comprehensive Cancer Network, GBM is the "deadliest brain tumor with only a third of patients surviving for 1 year and less than 5% living beyond 5 years."²

**Therapeutic Options**

The primary treatment for initial GBM is debulking surgery to remove as much of the tumor as possible. At that time, some patients may undergo implantation of the tumor cavity with a carmustine (bischloroethylnitrosourea [BCNU])-impregnated wafer.² Depending on the patient’s physical condition, adjuvant radiotherapy, chemotherapy (typically temozolomide), or a combination of the 2 are sometimes given. After adjuvant therapy, some patients may undergo maintenance therapy with temozolomide.

No standard treatment exists for recurrent GBM. In patients with disease that recurs after initial treatment, additional debulking surgery may be used if recurrence is localized. Other treatment options for recurrent disease include various forms of systemic medications such as bevacizumab, bevacizumab plus chemotherapy (eg, irinotecan, BCNU/chloroethylnitrosourea [CCNU], temozolomide), temozolomide, nitrosourea, PCV (procarbazine, CCNU, vincristine), cyclophosphamide, and platinum-based agents.² External beam radiotherapy also may be used to treat recurrent GBM. Response rates in recurrent disease are less than 10%, and progression-free survival rates at 6 months are less than 20%.²,³

**Tumor Treatment Fields Therapy**

TTF therapy is a noninvasive technology intended to treat GBM on an outpatient basis using electrical fields.³⁵ TTF therapy exposes cancer cells to alternating electric fields of low intensity and intermediate frequency, which are purported to both selectively inhibit tumor growth and reduce tumor angiogenesis.
TTF are proposed to inhibit rapidly dividing tumor cells by 2 mechanisms: arrest of cell proliferation and destruction of cells while undergoing division.4,5

The NovoTTF-100A System has received marketing approval from the U.S. Food and Drug Administration to deliver TTF therapy. TTF therapy via the NovoTTF-100A System is delivered by a battery-powered, portable device that generates the fields via disposable electrodes noninvasively attached to the patient’s shaved scalp over the site of the tumor.3,4 The device is used by the patient at home on a continuous basis (20-24 h/d) for the duration of treatment, which can last for several months. Patients can carry the device in a backpack or shoulder pack while carrying out activities of daily living.3,4

Summary
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 of treatment. Tumor treatment fields (TTF) therapy is a new, noninvasive technology intended to treat glioblastoma using alternating electric fields.

For individuals who have advanced or recurrent GBM who receive TTF therapy as an alternative to standard chemotherapy, the evidence includes 1 randomized controlled trial (RCT) and nonrandomized comparative studies. Relevant outcomes are overall survival, disease-specific survival, quality of life, and treatment-related morbidity. The single published RCT reported no differences in outcomes between patients treated with TTF and standard chemotherapy. This trial had several methodologic limitations. Comparisons made only included an active control of questionable efficacy, which may not reflect current standard of care. There was high dropout (>20% of patients in each group were lost to follow-up) and, for the quality of life outcomes, only approximately 25% of enrolled patients had complete data. The 2 nonrandomized studies were small and had limited validity due to differences in the patient populations treated with TTF and standard care. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have GBM on maintenance therapy after initial treatment with surgery and/or radiotherapy who receive TTF therapy as an adjunct to standard maintenance therapy, the evidence includes 1 RCT. Relevant outcomes include overall survival, disease-specific survival, symptoms, functional outcomes, quality of life, and treatment-related morbidity. The single RCT reported that patients who received TTF treatment plus temozolomide had longer progression-free survival (3.1 months) and overall survival (4.9 months) than patients who received temozolomide alone. The trial had methodologic limitations, including a lack of a placebo control, differential dropout between groups, and the possibility of adherence bias for outcomes reported with per protocol analysis. Further corroboration of these results is needed in high-quality RCTs. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>10/2016</td>
<td>BCBSA National medical policy review. Policy statements rewritten for clarity but tumor treating fields remains investigational for all indications. 10/1/2016.</td>
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<tr>
<td>11/2015</td>
<td>New references added from BCBSA National medical policy.</td>
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<tr>
<td>5/2015</td>
<td>Local Coverage Determination (LCD): Tumor Treatment Field Therapy (TTFT) (L34730) added. Coding information clarified.</td>
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<td>10/2014</td>
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Information Pertaining to All Blue Cross Blue Shield Medical Policies
Click on any of the following terms to access the relevant information:
Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References