Medical Policy
Tumor-Treatment Fields Therapy for Glioblastoma

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Policy Number: 514
BCBSA Reference Number: 1.01.29

Related Policies
- Autologous Hematopoietic Stem Cell Transplantation for Malignant Astrocytomas and Gliomas, #159

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

Tumor treatment fields therapy to treat glioblastoma is INVESTIGATIONAL.

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.

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

Local Coverage Determination (LCD): Tumor Treatment Field Therapy (TTFT) (L34730)
CPT Codes / HCPCS Codes / ICD-9 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.

Description
Glioblastoma multiforme is the most common and deadly malignant brain tumor. It has a very poor prognosis and is associated with low quality of life during the course of treatment. Tumor-treatment fields therapy is a new, noninvasive technology that is intended to treat glioblastoma using electrical fields.

Background
Glioblastomas, also known as glioblastoma multiforme (GBM), are the most common form of malignant primary brain tumor in adults, and 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 (NCCN), GBM is the "deadliest brain tumor with only a third of patients surviving for one year and less than 5% living beyond 5 years." (2)

The primary treatment for 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 (BCNU) - impregnated wafer. (2) Depending on the patient's physical condition, adjuvant radiation therapy, chemotherapy (typically temozolomide), or a combination of the two are sometimes given. After adjuvant therapy, some patients may undergo maintenance therapy with temozolomide. In patients with disease that recurs after these initial therapies, additional debulking surgery may be used if recurrence is localized. Treatment options for recurrent disease include various forms of systemic medications such as bevacizumab, bevacizumab plus chemotherapy (e.g., irinotecan, BCNU/CCNU, temozolomide), temozolomide, nitrosourea, PCV (procarbazine, CCNU, and vincristine), cyclophosphamide, and platinum-based agents. (2) 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 (TTF) therapy is a new, noninvasive technology that is intended to treat GBM on an outpatient basis using electrical fields. (3-5) 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. Tumor-treatment fields are proposed to inhibit rapidly dividing tumor cells by two mechanisms, arrest of cell proliferation and destruction of cells while undergoing division. (4, 5)

The NovoTTF-100A™ System (Novocure Ltd., Haifa, Israel) has been approved by the U.S. Food and Drug Administration (FDA) 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 that are 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 hours per day) 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
Tumor-treatment fields (TTF) therapy is a new noninvasive technology using electrical fields for treating recurrent glioblastoma. The available evidence consists of small case series and one randomized controlled superiority trial based on the FDA-approved device. This trial had numerous methodologic limitations and failed to demonstrate an improvement in overall survival or disease response. There were some differences reported in quality of life (QOL), but these data were limited by a low response rate for QOL measures. In addition, the best standard chemotherapy protocols reported in the randomized controlled trial may not reflect current practice, given the increased use of bevacizumab and temozolomide for treatment of patients with recurrent glioblastoma. No data were available to address a comparison to other third-line treatment modalities (i.e., radiation, surgery, combination therapy).

Further evidence from high-quality trials is needed to assess the long-term safety and efficacy of TTF. There are currently ongoing clinical trials of the TTF therapy including an ongoing post-marketing non-inferiority study that will provide additional data on outcomes of interest. Based on the small amount of evidence and lack of demonstrated treatment benefit to date, the use of TTF therapy for glioblastoma is considered investigational.

Policy History

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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