Medical Coverage Policy | Tumor Treatment Fields Therapy for Glioblastoma

EFFECTIVE DATE: 01|20|2014
POLICY LAST UPDATED: 08|01|2017

OVERVIEW
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 the course of treatment. Tumor treating fields (TTF) therapy is a new, noninvasive technology that is intended to treat glioblastoma using electric fields.

MEDICAL CRITERIA
None

PRIOR AUTHORIZATION
Not Applicable

POLICY STATEMENT
BlueCHiP for Medicare and Commercial Products:
TumorTreatiment Fields Therapy for the treatment of Glioblastoma, as an alternative to standard chemotherapy or as an adjunct to standard maintenance therapy following initial treatment with surgery and/or radiotherapy is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

TumorTreatment Fields Therapy for the treatment of Glioblastoma as an adjunct to standard maintenance therapy in patients with newly diagnosed glioblastoma multiforme following initial treatment with surgery, radiotherapy, and/or chemotherapy as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE
Benefits vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for
services not medically necessary.

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. 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. 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.

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. 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. Response rates in recurrent disease are less than 10%, and progression-free survival rates at 6 months are less than 20%.

Tumor treating 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 treating fields are proposed to inhibit rapidly dividing tumor cells by two mechanisms, arrest of cell proliferation and destruction of cells while undergoing division.

Optune®, formerly NovoTTF-100A System (Novocure, Haifa, Israel) is the only legally marketed TTF delivery system available in the United States. Optune® is a portable battery or power supply operated device that produces alternating electrical fields within the human body. These fields are called tumor treatment fields and are applied to the patient's shaved head by means of electrically insulated surface transducer arrays, such that resistively coupled electric currents are not delivered to the patient. The device is used by the patient at home on a continuous basis (20-24 hours a day for the duration of treatment). Patients can carry the device in a backpack or shoulder pack while carrying out activities of daily living.

Relevant outcomes are overall survival, disease-specific survival, quality of life, and treatment-related morbidity. The single RCT reported that patients who received TTF therapy plus temozolomide have 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 the lack of placebo control, differential dropout between groups, and the possibility of adherence bias for outcomes reported with per protocol analysis. Further corroboration of these results are needed in high-quality RCTs. The evidence is insufficient to determine the effects of the technology on health outcomes and is considered not medically necessary.

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 is insufficient to determine the effects of the technology on health outcomes and is considered not medically necessary.

CODING

BlueCHiP for Medicare and Commercial Products

The following codes are not medically necessary

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

RELATED POLICIES

None

PUBLISHED

Provider Update, September 2017
Provider Update, October 2016
Provider Update, April 2015
Provider Update, March 2014

REFERENCES

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