

**EFFECTIVE DATE: POLICY LAST UPDATED: 1/9/2014**

## **OVERVIEW**

This policy documents coverage guidelines for Tumor-Treatment Fields Therapy for Glioblastoma, also known as Novocure.

## **PRIOR AUTHORIZATION**

Not applicable

## **POLICY STATEMENT**

BlueCHiP for Medicare and Commercial Products:

Tumor-Treatment Fields Therapy for the treatment of Glioblastoma is considered not medically necessary as there is insufficient peer reviewed scientific literature that demonstrates that the procedure/service is effective.

## **MEDICAL CRITERIA**

None

## **BACKGROUND**

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. 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."

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.

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.

Based on the small amount of evidence and lack of demonstrated treatment benefit, the use of TTF therapy for glioblastoma is considered not medically necessary.

### COVERAGE

Benefits vary between groups/contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for applicable services not medically necessary coverage.

### CODING

There are no specific codes for this system, and claims should be submitted with the following unlisted codes

**E1399:** Miscellaneous durable medical equipment (DME) code

**A9900:** replacement transducer arrays are reported with the miscellaneous DME supply, accessory and/or service code.

### RELATED POLICIES

None

### PUBLISHED

Provider Update      Mar 2014

### REFERENCES

1. Novo TTF-100A System  
<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm254480.htm>
2. <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm251669.htm>
3. National Cancer Institute (NCI) - Adult Brain Tumors Treatment (PDQ®). Last modified May 14, 2013. Available online at:  
<http://www.cancer.gov/cancertopics/pdq/treatment/adultbrain/HealthProfessional>. Last accessed June 2013.
4. National Comprehensive Cancer Network (NCCN). Central nervous system cancers. NCCN Clinical Practice Guidelines in Oncology. Version 2.2013. For additional information visit the NCCN website at: <http://www.nccn.org/index.asp>. Last accessed June 2013.
5. Davies AM, Weinberg U, Palti Y. Tumor treating fields: a new frontier in cancer therapy. *Ann N Y Acad Sci* 2013.

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