

EFFECTIVE DATE: 10|01|2018
POLICY LAST UPDATED: 08|07|2018

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

MEDICAL CRITERIA

BlueCHiP for Medicare and Commercial Products:

Tumor treating fields therapy to treat glioblastoma multiforme is considered medically necessary as an adjunct to standard maintenance therapy with temozolomide in patients with newly diagnosed glioblastoma multiforme following initial treatment with surgery, radiotherapy, and/or chemotherapy when **all** of the following criteria are met:

- Adult patients ≥ 18 years of age
- Supratentorial tumor
- Karnofsky Performance Status score $\geq 70\%$ *
- Patient understands device use, including the requirement for a shaved head, and is willing to comply with to the Food and Drug Administration label guideline to use Optune for at least 18 hours a day and should finish at least 4 full weeks of therapy to get the best response to treatment.

APPROVAL PERIOD: 6 months. Services beyond the 6 months will need a new review and meet the above criteria.

*KARNOFSKY PERFORMANCE STATUS SCALE DEFINITIONS RATING (%) CRITERIA

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

Prior authorization is required for BlueCHiP for Medicare and recommended for Commercial Products

POLICY STATEMENT

BlueCHiP for Medicare and Commercial Products:

Tumor treating fields therapy is medically necessary when the above criteria is met.

BlueCHiP for Medicare

Tumor treating fields therapy is considered not covered in all other conditions, including but not limited to the following situations:

- As an adjunct to standard medical therapy (eg, bevacizumab, chemotherapy) for patients with progressive or recurrent glioblastoma multiforme
- As an alternative to standard medical therapy for patients with progressive or recurrent glioblastoma multiforme
- For brain metastases
- For cancer in areas other than the brain.

Commercial Products:

Tumor treating fields therapy is considered not medically necessary in all other conditions, including but not limited to the following situations:

- As an adjunct to standard medical therapy (eg, bevacizumab, chemotherapy) for patients with progressive or recurrent glioblastoma multiforme
- As an alternative to standard medical therapy for patients with progressive or recurrent glioblastoma multiforme
- For brain metastases
- For cancer in areas other than the brain.

COVERAGE

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

BACKGROUND

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 newly diagnosed GBM on maintenance therapy after initial treatment who receive TTF therapy as an adjunct to standard maintenance therapy, the evidence includes a randomized controlled trial (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.

CODING

BlueCHiP for Medicare and Commercial Products

The following code is medically necessary/covered when criteria is met.

E0766: Electrical stimulation device used for cancer treatment, includes all accessories, any type

The following code is covered when the service is approved

A4555: Electrode/transducer for use with electrical stimulation device used for cancer treatment, replacement only

RELATED POLICIES

None

PUBLISHED

Provider Update, September 2018

Provider Update, September 2017

Provider Update, October 2016

Provider Update, April 2015

Provider Update, March 2014

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