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Original Effective Date: 10/15/15

Reviewed: 08/22/24

Revised: 09/15/25

Subject: Tumor Treating Fields Therapy

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Glioblastomas, also known as glioblastoma multiforme (GBM), are the most common form of malignant primary brain tumor in adults. GBMs are grade IV astrocytomas, and are often resistant to standard chemotherapy.

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

TTF therapy is a noninvasive technology that is intended to treat GBM on an outpatient basis using electrical fields. TTF therapy exposes rapidly dividing cancer cells to electric fields of low intensity and intermediate frequency that alternate in perpendicular orientation. TTF is proposed to inhibit rapidly dividing tumor cells by 2 mechanisms, arrest of cell proliferation and destruction of cells while undergoing division.

Treatment planning software (eg, NovoTAL) is available and designed to be utilized prior to starting TTF treatment. NovoTAL is optional software that a physician can purchase and use to create individualized treatment maps. It is purported to allow the physician to individualize treatment by determining optimal placement of the transducer arrays, based on the individual's most recent magnetic resonance imaging (MRI) scan, head size and tumor location

REGULATORY STATUS

The Optune™ (formerly NovoTTF-100A System) System was approved by the FDA in April 2011, as a stand-alone treatment for adults age 22 years or older with confirmed GBM that recurs or progresses after surgical and radiation options have been exhausted. In October 2015, the FDA granted approval for use of Optune™ in combination with temozolomide to treat adults age 22 years or older with newly diagnosed GBM. In July 2016, a smaller, lighter version of the Optune® device, called the Optune® System, received FDA approval.

The Food and Drug Administration label includes the following notices:

- "Patients should use Optune for at least 18 hours a day to get the best response to treatment"
- "Patients should finish at least 4 full weeks of therapy to get the best response to treatment (stopping treatment before 4 weeks lowers the chances of a response to treatment)"

POSITION STATEMENT:

The use of tumor treating fields therapy (TTF) to treat newly diagnosed glioblastoma multiforme (GBM) **meets the definition of medical necessity** when **ALL** of the following criteria are met:

- The device is FDA approved
- Age 22 or older
- There is histologically-confirmed supratentorial glioblastoma (also known as glioblastoma multiforme [GBM] or World Health Organization [WHO] grade IV astrocytoma)
- Initial treatment with debulking surgery or biopsy followed by chemoradiation with concomitant temozolomide and radiotherapy has been completed, with no documented tumor progression*
- TTF is used in combination with temozolomide
- Karnofsky Performance Status score of 70% or higher, OR Eastern Cooperative Oncology Group (ECOG) performance status 0-1

* Progression is defined as tumor growth greater than 25% compared to smallest measured tumor area, or the appearance of one or more new GBM lesions in the brain.

The use of tumor treating fields therapy (TTF) to treat glioblastoma multiforme recurrence **meets the definition of medical necessity** when **ALL** of the following criteria are met:

- The device is FDA approved
- Age 22 or older
- There is histologically-confirmed recurrence of supratentorial glioblastoma (also known as glioblastoma multiforme [GBM] or World Health Organization [WHO] grade IV astrocytoma) following treatment with chemotherapy and/or radiation
- TTF is used as monotherapy

The use of tumor treating fields therapy (TTF) for all other indications is considered **experimental or investigational**. There is insufficient clinical evidence in the peer-reviewed literature on this technology to support its safety, effectiveness, and long term effects on net health outcomes for other types of cancer.

The use of treatment planning software (eg, NovoTAL) for use with tumor treatment fields for any indication is considered **experimental or investigational.** Data in published medical literature are inadequate to permit scientific conclusions on long-term and net health outcomes.

BILLING/CODING INFORMATION:

HCPCS Coding

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

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: The following Local Coverage Determination (LCD) was reviewed on the last guideline reviewed date: Tumor Treatment Field Therapy (TTFT) (L34823), located at cms.gov.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

DEFINITIONS:

Eastern Cooperative Oncology Group (ECOG) Performance Status

A scale used to determine an individual's level of functioning.

0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
2	Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours
3	Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
4	Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
5	Dead

Karnofsky Performance Status Score

A scale used by healthcare providers to quickly evaluate how an individual is feeling on any given day.

100	Normal, no complaints
90	Able to carry on normal activities. Minor signs or symptoms of disease
80	Normal activity with effort
70	Care for self. Unable to carry on normal activity or to do active work
60	Requires occasional assistance, but able to care for most of his needs
50	Requires considerable assistance and frequent medical care
40	Disabled. Requires special care and assistance
30	Severely disabled. Hospitalisation indicated though death nonimminent
20	Very sick. Hospitalisation necessary. Active supportive treatment necessary
10	Moribund
0	Dead

RELATED GUIDELINES:

None.

OTHER:

None.

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 08/22/24.

GUIDELINE UPDATE INFORMATION:

10/15/15	New Medical Coverage Guideline.
04/15/17	Scheduled review. Revised Description section. Added coverage criteria for TTF therapy. Revised Program Exceptions section and Definitions section. Updated references.
05/15/18	Scheduled review. Added coverage statement (E/I) for treatment planning software (eg, NovoTAL). Updated references.
05/15/19	Scheduled review. Revised MCG title and description. Maintained position statement and updated references.
05/15/20	Scheduled review. Maintained position statement and updated references.
07/15/21	Scheduled review. Maintained position statement and updated references.
11/15/22	Scheduled review. Revised description, maintained position statement and updated references.
05/25/23	Update to Program Exceptions section.
09/15/24	Scheduled review. Maintained position statement and updated references.
10/15/25	Revision. Updated references for the use of TTFT treatment for non-small cell lung cancer. Maintained position statement.