

<b>Policy Name:</b>	<b>Electric Tumor Treatment Fields (Optune®)</b>
<b>Effective Date:</b>	<b>12/19/2022</b>

**Important Information – Please Read Before Using This Policy**

These services may or may not be covered by all Medica plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member’s plan document for other specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment.

**Coverage Policy**

Electric tumor treatment fields in individuals 22 years of age or older for the treatment of newly diagnosed, histologically-confirmed supratentorial glioblastoma following debulking surgery and completion of radiation therapy, in conjunction with chemotherapy, **is COVERED**.

Electric tumor treatment fields in individuals 22 years of age or older for the treatment of histologically- or radiologically-confirmed recurrent supratentorial glioblastoma as monotherapy, after surgical, chemotherapy, and radiological treatment have been exhausted, **is COVERED**.

Electric tumor treatment fields for all other indications, including but not limited to other malignant tumors, is investigative and unproven and therefore **NOT COVERED**. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

**Description**

Glioblastoma (GBM, glioblastoma multiforme, grade IV astrocytoma) is a rapidly-growing type of central nervous system tumor that forms from glial (supportive) tissue of the brain and spinal cord. It is most common in older individuals and more common in men than women, with a median survival rate of approximately 15 months; 5-year survival rate is approximately 4%. The incidence of new diagnoses made annually is 2 to 3 per 100,000 people in the United States and Europe. Glioblastoma accounts for 12% to 15% of all intracranial tumors and 50% to 60% of astrocytic tumors. The exact cause of glioblastoma is not known. Treatment includes surgery, radiation therapy, and chemotherapy.

Electric tumor treatment fields (TTF) is a technology that applies low-intensity alternating electric fields to the brain, and purportedly disrupts the division of cancer cells. The Optune system consists of four sets of insulated electrodes (transducer arrays) and a generator. The arrays attach to the patient’s shaved scalp and are connected to the generator by wires. The patient wears the device continuously while treatment is being delivered (20-24 hours per day), for at least four weeks, and treatment can last as long as several months. It is theorized that the application of the alternating electric fields disrupts the division of cancer cells in the brain.

## FDA Approval

The Optune System, previously known as the NovoTTF-100A System, was given pre-market approval by the FDA in August 2010. It is intended for the treatment of adult patients (22 years of age or older) with histologically-confirmed glioblastoma multiforme, following histologically-or radiologically confirmed recurrence in the supratentorial region of the brain after receiving chemotherapy. The device is intended to be used as a monotherapy, and is intended as an alternative to standard therapy after surgical and radiation options have been exhausted. In 2013, the FDA approved a supplement for the NovoTAL, “a workstation-based proprietary software tool that uses MRI head morphology, tumor size and location measurements, and tissue dielectric properties to optimize TTF distribution and intensity within the target tumor.”

On October 5, 2015, the FDA approved an expanded indication for the Optune device to treat patients with newly-diagnosed glioblastoma. For newly diagnosed GBM, Optune is not intended to be used as a substitute for standard treatments, but rather as an adjunct therapy.

## Prior Authorization

Prior authorization is not required. However, services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial may result if criteria are not met.

## Coding Considerations

Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

### CPT Codes:

- **77299** - Unlisted procedure, therapeutic radiology clinical treatment planning
- **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

Original Effective Date Coverage Policy: 2/1/2016  
Re-review Date(s) Coverage Policy: 10/16/2019

Original Effective Date UM Policy: 6/1/2016  
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