Electric Tumor Treatment Field Therapy (for Kentucky Only)

Policy Number: CS146KY.06
Effective Date: March 1, 2024

Instructions for Use

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Related Policy

- Clinical Trials (for Kentucky Only)

Application

This Medical Policy only applies to the state of Kentucky.

Coverage Rationale

Electric tumor treatment field therapy is considered proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Durable Medical Equipment, Tumor Treatment Field Therapy (TTFT) Devices.

Click here to view the InterQual® criteria.

Note: This device meets FDA indications to treat adults only, age 22 years or older, with glioblastoma (GBM) that recurs or progresses after receiving chemotherapy and radiation therapy.

Computer software used for therapeutic radiology clinical treatment planning in conjunction with electric TTF therapy is unproven and not medically necessary due to insufficient evidence of efficacy.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
77299	Unlisted procedure, therapeutic radiology clinical treatment planning

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HCPCS Code	Description
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

Description of Services

Electric tumor treatment field (TTF) therapy (also known as tumor-treating fields, TTFields, ETTFs) is based on the principle that low intensity, intermediate frequency electric fields (100 to 300 kHz) disrupt cell division and may destroy proliferating cells in brain tumors (Rulseh et al, 2012).

Glioblastoma multiforme (GBM) is the most prevalent and primary malignant brain tumor in adults. For patients with newly diagnosed glioblastoma the initial standard treatment consists of debulking surgery (when feasible), followed by radiation and chemotherapy (NCCN, 2023).

The Optune® Treatment Kit, formerly the NovoTTF-100A System, (Novocure) was approved by the FDA in April 2011, as a novel device to treat adults age 22 years or older with GBM that recurs or progresses after receiving chemotherapy and radiation therapy. The Optune Treatment Kit has also been approved by the FDA in combination with Temozolomide in adult patients with newly diagnosed, Supratentorial glioblastoma following maximal debulking surgery and completion of radiation therapy. For newly diagnosed GBM, Optune is not intended to be used as a substitute for standard treatments but rather as an adjunct therapy (Novocure, 2020).

Refer to the U.S. Food and Drug Administration (FDA) section for additional information.

The Optune kit contains the portable electric field generator (Optune device), INE (insulated electrode) transducer arrays, power supply, and additional supplies. Prior to treatment, transducer arrays are placed on the individual's scalp according to the tumor's location, which are then covered by a lightweight white cap which resembles a bandage. The individual receives the noninvasive TTF treatment for at least 18 continuous hours per day for a minimum of four weeks. As the Optune device is portable, individuals are able to carry out every-day activities.

Treatment parameters are preset by the manufacturer such that there are no electrical output adjustments available to the individual being treated. The individual being treated or caregiver must learn to change and recharge depleted device batteries and to connect to an external power supply overnight. In addition, the transducer arrays need to be replaced once to twice a week and the scalp re-shaved in order to maintain optimal contact.

The NovoTAL™ (transducer array layout) system is optional simulation software for use in clinical treatment planning with Optune therapy that may be leased from the manufacturer. Its purpose is to determine the optimal location of the transducer arrays based on the individual's most recent magnetic resonance imaging (MRI) scan, head size, and tumor location.

TTF technology is also being studied through ongoing clinical trials as a treatment for other solid tumors such as non-small cell lung cancer, brain metastasis, pancreatic cancer, ovarian cancer, and mesothelioma.

Clinical Evidence

NovoTAL™ Simulation System

There is limited published clinical evidence related to the NovoTAL™ simulation system, and insufficient data to support improved long-term health outcomes with its use. This includes a small case series (Connelly et al., 2016), human head model (Wenger et al., 2016), and a user group survey (Chaudhry et al., 2015). A framework for the use of NovoTAL in treatment planning has been proposed by Trusheim et al. (2016).

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

The Optune Treatment Kit, formerly the NovoTTF-100A System, (Novocure) was approved by the FDA in April 2011, as a novel device to treat adults age 22 years or older with glioblastoma (GBM) that recurs or progresses after receiving chemotherapy and radiation therapy. The Optune is categorized by the FDA as a stimulator, low electric field, tumor treatment; refer to the following website for the initial Premarket Approval information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P100034. (Accessed June 5, 2023)

A supplemental FDA premarket approval was received in October 2015 for Optune with Temozolomide in adults with newly diagnosed, Supratentorial glioblastoma following maximal debulking surgery and completion of radiation therapy together with concomitant standard of care chemotherapy. Refer to the following website for more information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P100034S013. (Accessed June 5, 2023)

The FDA has approved a humanitarian device exemption (HDE) application for the NovoTTF™-100L System for mesothelioma. Refer to the following website for more information: https://www.accessdata.fda.gov/cdrh_docs/pdf18/H180002B.pdf. (Accessed June 5, 2023)

Refer to the following website for additional information on supplemental FDA approvals for the Optune using product code NZK: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm. (Accessed June 5, 2023)

NovoTAL simulation software is not regulated by the FDA.

References

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Connelly J, Hormigo A, Mohilie N, et al. Planning TTFields treatment using the NovoTAL system-clinical case series beyond the use of MRI contrast enhancement. BMC Cancer. 2016 Nov 4;16(1):842.

ECRI Institute. Custom Product Brief. Optune treatment kit (Novocure, Ltd.) for treating newly diagnosed glioblastoma. January 2019.

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National Comprehensive Cancer Network (NCCN). NCCN Clinical practice guidelines in oncology (NCCN Guidelines®). Central nervous system cancers. v1. 2023. March 24, 2023.

Trusheim J, Dunbar E, Battiste J, et al. A state-of-the-art review and guidelines for tumor treating fields treatment planning and patient follow-up in glioblastoma. CNS Oncol. 2017 Jan;6(1):29-43.

Wenger C, Salvador R, Basser PJ, et al. Improving tumor treating fields treatment efficacy in patients with glioblastoma using personalized array layouts. Int J Radiat Oncol Biol Phys. 2016 Apr 1;94(5):1137-43.

Policy History/Revision Information

Date	Summary of Changes
03/01/2024	**Supporting Information** • Updated *References* section to reflect the most current information • Archived previous policy version CS146KY.05

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state, or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state, or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state, or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state, or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare uses InterQual® for the primary medical/surgical criteria, and the American Society of Addiction Medicine (ASAM) for substance use, in administering health benefits. If InterQual® does not have applicable criteria, UnitedHealthcare may also use UnitedHealthcare Medical Policies, Coverage Determination Guidelines, and/or Utilization Review Guidelines that have been approved by the Kentucky Department for Medicaid Services. The UnitedHealthcare Medical Policies, Coverage Determination Guidelines, and Utilization Review Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.