Electric Tumor Treatment Field Therapy (for Kentucky Only)

Policy Number: CS146KY.07
Effective Date: January 1, 2025

Instructions for Use

Table of Contents **Page**

Application 1
Coverage Rationale 1
Applicable Codes 1
Description of Services 2
Clinical Evidence 2
U.S. Food and Drug Administration 2
References 2
Policy History/Revision Information 3
Instructions for Use 3

Related Policy

- Mandatory Medicaid Coverage of Routine Patient Costs in Qualifying Clinical Trials (for Kentucky Only)

Application

This Medical Policy only applies to the state of Kentucky.

Coverage Rationale

Electric tumor treatment field (TTF) 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

CPT® is a registered trademark of the American Medical Association

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
E0767	Intrabuccal, systemic delivery of amplitude-modulated, radiofrequency electromagnetic field device, for cancer treatment, includes all accessories

Description of Services

The NovoTAL™ (transducer array layout) system is an 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.

Clinical Evidence

NovoTAL™ Simulation System

The NovoTAL™ software utilizes magnetic resonance imaging (MRI) measurements for head size and tumor location obtained from axial and coronal T1 postcontrast sequences to determine the optimal paired transducer array configuration that will deliver the maximal field intensity at the tumor site. 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), a 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. (2017).

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 aged 22 years or older with glioblastoma (GBM) that recurs or progresses after receiving chemotherapy and radiation therapy. The FDA categorizes the Optune 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 May 14, 2024)

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 May 14, 2024)

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 May 14, 2024)

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 May 14, 2024)

References

Chaudhry A, Benson L, Varshaver M, et al. NovoTTF™-100A System (Tumor Treating Fields) transducer array layout planning for glioblastoma: a NovoTAL™ System user study. World J Surg Oncol. 2015;13:316.

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.

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
01/01/2025	**Applicable Codes** • Updated list of applicable HCPCS codes to reflect quarterly edits; added E0767 **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information • Archived previous policy version CS146KY.06

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.