PROVIDER POLICIES & PROCEDURES

ELECTRIC TUMOR TREATMENT FIELD THERAPY (E.G. OPTUNE DEVICE)

The purpose of this document is to assist providers enrolled in the Connecticut Medical Assistance Program (CMAP) with the information needed to support a medical necessity determination for electric tumor treatment field therapy. By clarifying the information needed for prior authorization of services, HUSKY Health hopes to facilitate timely review of requests so that individuals obtain the medically necessary care they need as quickly as possible.

Tumor treatment field (TTF) therapy uses a noninvasive device to create alternating, wave-like electric fields to selectively disrupt mitosis in dividing cancer cells. TTF is approved for use in the treatment of glioblastoma multiforme (GBM), the most prevalent and primary malignant brain tumor in adults. The device is comprised of an electric field generator, a connection cable and box, transducer arrays, and batteries along with a charger, power supply and carrying bag. The transducer arrays are directly applied to the scalp and must be changed at least two times per week. The device is portable for use in normal daily activities and is typically worn for at least 18 hours per day.

CLINICAL GUIDELINE

Coverage guidelines for TTF therapy are made in accordance with the Department of Social Services (DSS) definition of Medical Necessity. The following criteria are guidelines *only.* Coverage determinations are based on an assessment of the individual and their clinical needs. If the guidelines conflict with the definition of Medical Necessity, the definition of Medical Necessity shall prevail. The guidelines are as follows:

Use of a device to generate TTF is generally considered medically necessary for adults (at least 22 years of age) with histologically confirmed glioblastoma (World Health Organization grade IV astrocytoma) when used:

1. As monotherapy:
    A. Following histologically or radiologically confirmed recurrence in the supratentorial region of the brain after receiving chemotherapy; and
    B. When intended as an alternative to standard medical therapy after surgical and radiation options have been exhausted; **OR**
2. As adjunctive therapy with temozolomide for newly-diagnosed histologically confirmed supratentorial glioblastoma following debulking surgery and completion of radiation therapy together with concomitant standard chemotherapy.

Initial Coverage

When all of the above criteria are met, an initial 3 months of TTF therapy will be approved.

Continuing Coverage:

In addition to meeting the above criteria, subsequent approval(s) for continuation of TTF therapy is based on:

1. Evidence of no documented disease progression by MRI or if MRI contraindicated, as evidenced by clinical re-evaluation; and

2. Documentation that the individual has been wearing the device for at least 18 hours per day.

The use of a device to generate TTF is generally considered investigational and therefore not medically necessary for the treatment of other malignant tumors (e.g., breast, lung, melanoma, ovarian cancer, pancreatic cancer and solid tumor brain metastases) and for all other indications because the effectiveness has not been established.

The use of combined TTF therapy and chemo-immuno therapy other than temozolomide for the treatment of other malignant tumors is generally considered investigational and therefore not medically necessary because the effectiveness of this approach has not been established.

NOTE: EPSDT Special Provision
Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) is a federal Medicaid requirement that requires the Connecticut Medical Assistance Program (CMAP) to cover services, products, or procedures for Medicaid enrollees under 21 years of age where the service or good is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition identified through a screening examination. The applicable definition of medical necessity is set forth in Conn. Gen. Stat. Section 17b-259b (2011) [ref. CMAP Provider Bulletin PB 2011-36].

PROCEDURE
Prior authorization for TTF therapy is required. Coverage determinations will be based upon a review of requested and/or submitted case-specific information.

The following information is needed to review requests for TTF therapy:
1. Fully completed Outpatient Prior Authorization Request Form or fully completed authorization request via on-line web portal;
2. A prescription from a licensed physician enrolled in the Connecticut Medical Assistance Program (CMAP);
3. Clinical information supporting the medical necessity of the treatment;
4. Pricing information*;
5. Results of follow-up MRI or clinical re-evaluation (when requesting continuing coverage);
6. Documentation that the individual has been wearing the device for at least 18 hours per day (when requesting continuing coverage); and
7. Other information as requested.

***** Reimbursed at MSRP – 15%. Payment includes all necessary goods and services related to TTF therapy.

EFFECTIVE DATE
This Policy is effective for prior authorization requests for TTF therapy for individuals covered under the HUSKY Health Program beginning November 1, 2017.

LIMITATIONS
N/A

CODE:

Code	Description
E1399	Durable medical equipment, miscellaneous

DEFINITIONS

1. **HUSKY A**: Connecticut children and their parents or a relative caregiver; and pregnant women may qualify for HUSKY A (also known as Medicaid). Income limits apply.
2. **HUSKY B**: Uninsured children under the age of 19 in higher income households may be eligible for HUSKY B (also known as the Children's Health Insurance Program) depending on their family income level. Family cost-sharing may apply.
3. **HUSKY C**: Connecticut residents who are age 65 or older or residents who are ages 18-64 and who are blind, or have another disability, may qualify for Medicaid coverage under HUSKY C (this includes Medicaid for Employees with Disabilities (MED-Connect), if working). Income and asset limits apply.
4. **HUSKY D**: Connecticut residents who are ages 19-64 without dependent children and who: (1) do not qualify for HUSKY A; (2) do not receive Medicare; and (3) are not pregnant, may qualify for HUSKY D (also known as Medicaid for the Lowest-Income populations).
5. **HUSKY Health Program**: The HUSKY A, HUSKY B, HUSKY C, HUSKY D and HUSKY Limited Benefit programs, collectively.
6. **HUSKY Limited Benefit Program or HUSKY, LBP**: Connecticut's implementation of limited health insurance coverage under Medicaid for individuals with tuberculosis or for family planning purposes and such coverage is substantially less than the full Medicaid coverage.
7. **Medically Necessary or Medical Necessity**: (as defined in Connecticut General Statutes § 17b-259b) Those health services required to prevent, identify, diagnose, treat, rehabilitate or ameliorate an individual's medical condition, including mental illness, or its effects, in order to attain or maintain the individual's achievable health and independent functioning provided such services are: (1) Consistent with generally-accepted standards of medical practice that are defined as standards that are based on (A) credible scientific evidence published in peer-reviewed medical literature that is generally recognized by the relevant medical community, (B)recommendations of a physician-specialty society, (C) the views of physicians practicing in relevant clinical areas, and (D) any other relevant factors; (2) clinically appropriate in terms of type, frequency, timing, site, extent and duration and considered effective for the individual's illness, injury or disease; (3) not primarily for the convenience of the individual, the individual's health care provider or other health care providers; (4) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the individual's illness, injury or disease; and (5) based on an assessment of the individual and his or her medical condition.
8. **Prior Authorization**: A process for approving covered services prior to the delivery of the service or initiation of the plan of care based on a determination by CHNCT as to whether the requested service is medically necessary.

RESOURCES AND REFERENCES:

Government Agency, Medical Society and Other Authoritative Publications:

- Centers for Medicare and Medicaid Services (CMS), Health Care Procedural Coding System Level II Manual: 2019
- CGS Administrators, LLC. Local Coverage Determination (LCD) for Tumor Treatment Field

Therapy (TTFT) (L34823). Durable Medical Equipment Medicare Administrative Contractor (DME MAC) Jurisdiction C. Nashville, TN: October 1, 2015.
- National Cancer Institute (NCI). Adult Central Nervous System Tumors Treatment (PDQ). Health Professional Version. Bethesda, MD: NCI; updated August 26, 2016.
- National Comprehensive Cancer Network (NCCN). Central nervous system cancers. NCCN Clinical Practice Guidelines in Oncology. Version 1.2016. Fort Washington, PA: NCCN; 2016
- U.S. Food and Drug Administration (FDA). FDA approves expanded indication for medical device to treat a form of brain cancer. FDA News. Silver Spring, MD: FDA: October 5, 2015. Available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm465744.htm. Accessed June 20, 2017.
- U.S. Food and Drug Administration (FDA). FDA approves new medical device for form of brain cancer. FDA News. Silver Spring, MD: FDA: April 15, 2011. Available at: https://wayback.archive-it.org/7993/20170114063455/http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm251669.htm. Accessed June 20, 2017.

Peer Reviewed Publications

- Bomzon Z, Urman N, Wenger C, et al. Modelling tumor treating fields for the treatment of lung-based tumors. Conf Proc IEEE Eng Med Biol Soc. 2015;2015:6888-6891.
- Butowski N, Wong ET, Mehta MP, Wilson LK. A roundtable discussion on the clinical challenges and options for the treatment of glioblastoma: Introducing a novel modality, TTFields. Semin Oncol. 2013;40(6):S2-S4.
- Davies AM, Weinberg U, Palti Y. Tumor treating fields: A new frontier in cancer therapy. Ann N Y Acad Sci. 2013;1291:86-95.
- De Bonis P, Doglietto F, Anile C, et al. Electric fields for the treatment of glioblastoma. Expert Rev Neurother. 2012;12(10):1181-1184
- Elzinga G, Wong ET. Resolution of cystic enhancement to add-on tumor treating electric fields for recurrent glioblastoma after incomplete response to bevacizumab. Case Rep Neurol. 2014;6(1):109-115.
- Giladi M, Schneiderman RS, Porat Y, et al. Mitotic disruption and reduced clonogenicity of pancreatic cancer cells in vitro and in vivo by tumor treating fields. Pancreatology. 2014;14(1):54-63.
- Giladi M, Weinberg U, Schneiderman RS, et al. Alternating electric fields (tumor treating fields therapy) can improve chemotherapy treatment efficacy in non-small cell lung cancer both in vitro and in vivo. Semin Oncol. 2014;41(Suppl 6):S35-S41.
- Kirson ED, Dbaly V, Tovarys F, et al. Alternating electric fields arrest cell proliferation in animal tumor models and human brain tumors. Proc Natl Acad Sci U S A. 2007;104(24):10152-10157.
- Kirson ED, Gurvich Z, Schneiderman R, et al. Disruption of cancer cell replication by alternating electric fields. Cancer Res. 2004;64(9):3288-3295.
- Kirson ED, Schneiderman RS, Dbalý V, et al. Chemotherapeutic treatment efficacy and sensitivity are increased by adjuvant alternating electric fields (TTFields). BMC Med Phys. 2009;9:1
- Lacouture ME, Davis ME, Elzinga G, et al. Characterization and management of dermatologic adverse events with the NovoTTF-100A System, a novel anti-mitotic electric field device for the treatment of recurrent glioblastoma. Semin Oncol. 2014;41 Suppl 4:S1-14.
- Li J, Guo C, Wang Z, et al. Electrical stimulation towards melanoma therapy via liquid metal printed electronics on skin. Clin Transl Med. 2016;5(1):21.
- Omar AI. Tumor treating field therapy in combination with bevacizumab for the treatment of recurrent glioblastoma. J Vis Exp. 2014;(92):e51638.

- Pless M, Betticher DC, Buess M, et al. A phase II study of tumor-treating fields (TTFields) in combination with pemetrexed for advanced non-small cell lung cancer (NSCLC). ESMO; 2010. Abstract 371PD.
- Pless M, Droege C, von Moos R, et al. A phase I/II trial of Tumor Treating Fields (TTFields) therapy in combination with pemetrexed for advanced non-small cell lung cancer. Lung Cancer. 2013;81(3):445-450.
- Pless M, Weinberg U. Tumor treating fields: Concept, evidence and future. Expert Opin Investig Drugs. 2011;20(8):1099-106
- Ram Z, Gutin PH, Stupp R. Subgroup and quality of life analyses of the phase III clinical trial of NovoTTFields-100A versus best standard chemotherapy for recurrent glioblastoma. Neuro Oncol. 2010;12(Suppl 4):iv36-iv57
- Salzberg M, Kirson E, Palti Y, Rochlitz C. A pilot study with very low-intensity, intermediate-frequency electric fields in patients with locally advanced and/or metastatic solid tumors. Oncologie. 2008;31(7):362-365.
- Stupp R, Kanner A, Engelhard H, et al. A prospective, randomized, open-label, phase III clinical trial of NovoTTFields-100A versus best standard of care chemotherapy in patients with recurrent glioblastoma. J Clin Oncol. 2010;28(18S): Abstract LBA2007
- Stupp R, Tailibert S, Kanner A, et al. Maintenance therapy with tumor-treating fields plus temozolomide vs temozolomide alone for glioblastoma. A randomized clinical trial. JAMA. 2015;314:2535-2543.
- Stupp R, Weller M. 2010: Neuro-oncology is moving! Curr Opin Neurol. 2010;23(6):553-555
- Stupp R, Wong ET, Kanner AA, et al. NovoTTF-100A versus physician's choice chemotherapy in recurrent glioblastoma: A randomised phase III trial of a novel treatment modality. Eur J Cancer. 2012;48(14):2192-2202.
- Stupp R, Wong E, Scott C, et al. NT-40 Interim Analysis of the EF-14 Trial: A Prospective, Multi-center Trial of NovoTTF-100A Together With Temozolomide Compared to Temozolomide Alone in Patients with Newly Diagnosed GBM. Neuro Oncol. 2014;16 (suppl 5): v167.
- Turner SG, Gergel T, Wu H, et al. The effect of field strength on glioblastoma multiforme response in patients treated with the NovoTTF™-100A system. World J Surg Oncol. 2014;12:162.
- Vymazal J, Wong ET. Response patterns of recurrent glioblastomas treated with tumor treating fields (TTFields). Semin Oncol. 2014;41(Suppl 6):S14-S24.
- Wong ET, Lok E, Swanson KD. Clinical benefit in recurrent glioblastoma from adjuvant NovoTTF-100A and TCCC after temozolomide and bevacizumab failure: A preliminary observation. Cancer Med. 2015;4(3):383-391.

PUBLICATION HISTORY

Status	Date	Action Taken
Original Publication	September, 2017	Approved at the July 26, 2017 Medical Policy Review Committee meeting. Approved by the Clinical Quality Subcommittee on September 21, 2017. Approved by DSS on September 26, 2017.
Update	July 2018	Reference Update Approved at the July 25, 2018 Medical Policy Review Committee Meeting. Change approved by the CHNCT Clinical Quality Subcommittee on September 17, 2018. Approved by DSS on

		September 19, 2018.
Update	June 2019	Reference update. Change approved at the June 12, 2019 Medical Reviewer meeting. Change approved by the CHNCT Clinical Quality Subcommittee on June 19, 2019. Approved by DSS on June 21, 2019.