BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

MEDICAL COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 07/12/11**
SECTION: Durable Medical Equipment (DME)	**LAST REVIEW DATE: 09/02/14**
	LAST CRITERIA REVISION DATE: 07/09/13
	ARCHIVE DATE:

ELECTRIC TUMOR TREATMENT FIELDS

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

Description:

Electrical fields referred to as "Tumor Treatment Fields (TTF)" are low intensity, intermediate frequency alternating electric fields administered using insulated electrodes placed on the skin surrounding the region of a malignant tumor. TTFs were shown to destroy cells within the process of mitosis via apoptosis, thereby inhibiting tumor growth.

An example of an FDA approved TTF device, includes but is not limited to the NovoTTF™-100A System. This is a portable device investigated as a stand-alone treatment for recurrent glioblastoma multiforme (GBM) after surgical and radiation options have been exhausted. The device can be powered with batteries or plugged into an electrical outlet. It can be used by the individual at home, allowing them to continue their normal daily activities. It is designed to be worn for at least 4 weeks continuously and until clinical disease progression occurs. NovoTTF-100A System has also been investigated as a noninvasive treatment for other solid tumors.

ELECTRIC TUMOR TREATMENT FIELDS (cont.)

Criteria:

- Electric tumor treatment fields for the treatment of malignant tumors is considered ***experimental or investigational*** based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.

  These indications include, *but are not limited to:*

  - Glioblastoma multiforme (GBM)
  - Non-small cell lung cancer (NSCLC)

Resources:

1. 1.01.29 BCBS Association Medical Policy Reference Manual. Tumor-Treatment Fields Therapy for Glioblastoma. Re-issue date 08/14/2014; issue date 08/08/2013.

2. CancerNetwork Editors. First-in-Class Antimitotic Device Approved for Glioblastoma. *Cancer Network.* April 21, 2011.

3. Clinical Trial.Gov. Effect of NovoTTF-100A Together with Temozolomide in Newly Diagnosed Glioblastoma Multiforme (GBM) NCT00916409. Accessed 08/11/2014, 05/22/2013.

4. Clinical Trial.Gov. Effect of NovoTTF-100A in Non-small Cell Lung Cancer (NSCLC) Patients with 1-5 Brain Metastases Following Optimal Standard Local Treatment NCT01755624 Accessed 08/11/2014, 05/22/2013.

5. Clinical Trial.Gov. NovoTTF-100L in Combination with Pemetrexed (Alimta®) for Advanced Non-small Cell Lung Cancer. Accessed 08/11/2014, 05/22/2013.

6. Clinical Trials.Gov. Post-approval Study of Novo-TTF-100A in Recurrent GBM Patients NCT01756729. Accessed 08/11/2014, 05/22/2013.

ELECTRIC TUMOR TREATMENT FIELDS (cont.)

Resources: (cont.)

7. Davies AM, Weinberg U, Palti Y. Tumor treating fields: a new frontier in cancer therapy. *Ann N Y Acad Sci.* May 9 2013.

8. De Bonis P, Doglietto F, Anile C, Pompucci A, Mangiola A. Electric fields for the treatment of glioblastoma. *Expert Rev Neurother.* Oct 2012;12(10):1181-1184.

9. Fonkem E, Wong ET. NovoTTF-100A: a new treatment modality for recurrent glioblastoma. *Expert Rev Neurother.* Jun 19 2012.

10. Pless M, Droege C, von Moos R, Salzberg M, Betticher D. A phase I/II trial of Tumor Treating Fields (TTFields) therapy in combination with pemetrexed for advanced non-small cell lung cancer. *Lung Cancer.* Sep 2013;81(3):445-450.

11. Rulseh AM, Keller J, Klener J, et al. Long-term survival of patients suffering from glioblastoma multiforme treated with tumor-treating fields. *World J Surg Oncol.* 2012;10:220.

12. Stupp R, Kanner A, Engelhard H, et. al. A prospective, randomized, open-label, phase III clinical trial of NovoTTF-100A versus best standard of care chemotherapy in patients with recurrent glioblastoma. *J Clin Oncol.* 2010 2010;28:18s(suppl; abstr LBA2007).

13. Stupp R, Weller M. 2010: neuro-oncology is moving! *Curr Opin Neurol.* 2010 Dec 2010;23(6):553-555.

14. 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.* May 18 2012.

15. TEC Medical Policy Clearinghouse News. New Cancer Treatment Device (NovoTTF) Approved by FDA. April 22, 2011.

16. Villano JL, Williams LE, Watson KS, et al. Delayed response and survival from NovoTTF-100A in recurrent GBM. *Med Oncol.* Mar 2013;30(1):338.

ELECTRIC TUMOR TREATMENT FIELDS (cont.)

Resources: (cont.)

FDA Premarket Approval Database for NovoTTF-100A System:

- FDA-approved indication: For 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 medical therapy for gbm after surgical and radiation options have been exhausted.