



MEDICAL COVERAGE GUIDELINES
SECTION: Durable Medical Equipment (DME)

ORIGINAL EFFECTIVE DATE: 02/05/19
LAST REVIEW DATE:
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

TUMOR TREATING FIELDS THERAPY

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

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.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

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.

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered service marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. All other trademarks and service marks contained in this guideline are the property of their respective owners, which are not affiliated with BCBSAZ.

TUMOR TREATING FIELDS THERAPY (cont.)

Description:

Glioblastoma multiforme (GBM) is the most common and deadly malignant brain tumor. It has a very poor prognosis and is associated with low quality of life during treatment. Tumor treatment fields (TTF) therapy is a new, noninvasive technology intended to treat glioblastoma using alternating electric fields.

Electrical field therapy also referred to as Tumor Treatment Field therapy, exposes cancer cells to alternating electric fields of low intensity and intermediate frequency using insulated electrodes placed on the skin surrounding the region of a malignant tumor to inhibit tumor growth and reduce tumor angiogenesis. TTF inhibit rapidly dividing tumor cells by arrest of cell proliferation and destruction of cells while undergoing division.

FDA-approved TTF devices, include, *but are not limited to:*

- NovoTTF™-100A System
- Optune®

Criteria:

- Tumor treating fields therapy (TTF) to treat glioblastoma multiforme is considered **medically necessary** as an adjunct to standard maintenance therapy with temozolomide with documentation of **ALL** of the following:
 1. Newly diagnosed glioblastoma multiforme following initial treatment with surgery, radiotherapy, and/or chemotherapy
 2. Adults ≥18 years of age
 3. Karnofsky Performance Status¹ score ≥70%
 4. Supratentorial tumor
 5. Demonstrates understanding of device use, including requirement for a shaved head, and is willing to comply with use criteria according to the FDA label



MEDICAL COVERAGE GUIDELINES
SECTION: Durable Medical Equipment (DME)

ORIGINAL EFFECTIVE DATE: 02/05/19
LAST REVIEW DATE:
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

TUMOR TREATING FIELDS THERAPY (cont.)

Criteria: (cont.)

- Tumor treating fields therapy for all other indications not previously listed or if criteria above not met 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:*

- As an adjunct to standard medical therapy (e.g., bevacizumab, chemotherapy) for individuals with progressive or recurrent glioblastoma multiforme
- As an alternative to standard medical therapy for individuals with progressive or recurrent glioblastoma multiforme
- Brain metastases
- Cancer in areas other than the brain

- 1 Karnofsky Performance Status table is located at the end of the Criteria section.

Karnofsky Performance Score:

100%	Able to carry on normal activity, no evidence of disease.
90%	Able to carry on normal activity, minor signs or symptoms of disease.
80%	Normal activity with effort, some signs and symptoms of disease.
70%	Cares for self, unable to carry on normal activity or to work.
60%	Requires occasional assistance from others but able to care for most needs.
50%	Requires considerable assistance from others and frequent medical care
40%	Disabled, requires special care and assistance.
30%	Severely disabled, hospitalization indicated, death not imminent.
20%	Very sick, hospitalization indicated, active support treatment necessary.
10%	Moribund
0%	Dead



MEDICAL COVERAGE GUIDELINES
SECTION: Durable Medical Equipment (DME)

ORIGINAL EFFECTIVE DATE: 02/05/19
LAST REVIEW DATE:
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

TUMOR TREATING FIELDS THERAPY (cont.)

Resources:

Literature reviewed 08/21/18. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

1. 1.01.29 BCBS Association Medical Policy Reference Manual. Tumor-Treating Fields Therapy for Glioblastoma. Re-issue date 06/14/2018; issue date 08/08/2013.
2. CancerNetwork Editors. First-in-Class Antimitotic Device Approved for Glioblastoma. *Cancer Network*. April 21, 2011.
3. Clinical Trials.Gov. Safety and Efficacy of TTFIELDS Concomitant With Pemetrexed and Cisplatin or Carboplatin in Malignant Pleural Mesothelioma (STELLAR) NCT02397928. Accessed 09/02/2015.
4. Clinical Trial.Gov. Effect of NovoTTF-100A Together with Temozolomide in Newly Diagnosed Glioblastoma Multiforme (GBM) NCT00916409. Accessed 08/27/2015, 08/11/2014, 05/22/2013.
5. 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 08/27/2015, 08/11/2014, 05/22/2013.
6. Clinical Trial.Gov. NovoTTF-100L in Combination with Pemetrexed (Alimta®) for Advanced Non-small Cell Lung Cancer NCT00749346. Accessed 08/27/2015, 08/11/2014, 05/22/2013.
7. Clinical Trial.Gov. Safety, Feasibility and Effect of TTFIELDS Concomitant With Weekly Paclitaxel in Recurrent Ovarian Carcinoma (INNOVATE) NCT02244502. Accessed 09/02/2015.
8. Clinical Trials.Gov. Post-approval Study of Novo-TTF-100A in Recurrent GBM Patients NCT01756729. Accessed 08/27/2015, 08/11/2014, 05/22/2013.
9. Clinical Trials.Gov. Safety Feasibility and Effect of NovoTTF-100L Together With Gemcitabine for Front-line Therapy of Advanced Pancreatic Adenocarcinoma (PANOVA) NCT01971281. Accessed 09/02/2015.
10. Davies AM, Weinberg U, Palti Y. Tumor treating fields: a new frontier in cancer therapy. *Ann N Y Acad Sci*. May 9 2013.
11. 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.



MEDICAL COVERAGE GUIDELINES
SECTION: Durable Medical Equipment (DME)

ORIGINAL EFFECTIVE DATE: 02/05/19
LAST REVIEW DATE:
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

TUMOR TREATING FIELDS THERAPY (cont.)

Resources: (cont.)

12. Fonkem E, Wong ET. NovoTTF-100A: a new treatment modality for recurrent glioblastoma. *Expert Rev Neurother.* Jun 19 2012.
13. NCCN National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) Central Nervous System Cancers Version 1.2016.
14. 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.
15. 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.
16. 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).
17. Stupp R, Taillibert S, Kanner AA, et al. Maintenance Therapy With Tumor-Treating Fields Plus Temozolomide vs Temozolomide Alone for Glioblastoma: A Randomized Clinical Trial. *JAMA.* Dec 15 2015;314(23):2535-2543.
18. Stupp R, Weller M. 2010: neuro-oncology is moving! *Curr Opin Neurol.* 2010 Dec 2010;23(6):553-555.
19. 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.
20. TEC Medical Policy Clearinghouse News. New Cancer Treatment Device (NovoTTF) Approved by FDA. April 22, 2011.
21. UpToDate.com. Management of recurrent high-grade gliomas. 08/26/2016.
22. UpToDate.com. Initial postoperative therapy for glioblastoma and anaplastic astrocytoma. 08/26/2016.
23. 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.



MEDICAL COVERAGE GUIDELINES
SECTION: Durable Medical Equipment (DME)

ORIGINAL EFFECTIVE DATE: 02/05/19
LAST REVIEW DATE:
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

TUMOR TREATING FIELDS THERAPY (cont.)

Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nilinígíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idííkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idííkidgo beehaz'áanii hóloq díí t'áa hazaadk'ehjí háká a'doowołgo bee haz'ą doo baqah ilínígóó. Ata' halne'ígíí kojí' bich'í' hodíilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.

