

Policy: MP306

Section: Medical Benefit Policy

Subject: Tumor Treatment Fields

Applicable Lines of Business

Commercial	X	CHIP	X
Medicare	X	ACA	X
Medicaid	X		

I. Policy: Tumor Treatment Fields

II. Purpose/Objective:

To provide a policy of coverage regarding Tumor Treatment Fields

III. Responsibility:

- A. Medical Directors
- B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.

- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:

Tumor Treating Fields, or TTF are low intensity, alternating electric fields within the intermediate frequency range. TTF disrupts cell division through physical interactions with key molecules during mitosis. TTF are generated via pairs of transducer arrays placed directly on the skin’s surface in the region surrounding the tumor. The Optune™ delivery system is portable and is designed to allow individuals to continue their daily activities while receiving treatment. This non-invasive treatment is intended as a treatment for adults with histologically-confirmed glioblastoma multiforme (GBM). GBM includes: giant cell glioblastoma, gliosarcoma and epithelioid glioblastoma.

INDICATIONS: REQUIRES PRIOR AUTHORIZATION BY A PLAN MEDICAL DIRECTOR OR DESIGNEE

COMMERCIAL AND MEDICARE BUSINESS SEGMENTS:

ALL Durable Medical Equipment provided for home use requires advanced determination of coverage. Devices furnished at inpatient or outpatient centers are NOT SEPARATELY REIMBURSABLE.

The Optune™ tumor treatment field delivery system may be considered medically necessary when **all of the following** criteria are met:

1. As concomitant therapy with temzolomide in newly diagnosed, supratentorial glioblastoma multiforme following maximal debulking surgery and completion of radiation therapy; **and**
 - Member is an adult (defined by the FDA for this device as age 22 years or older); **and**
 - Karnofsky Performance Scale* score of 60 (70 for Medicare) or greater, or Eastern Cooperative Oncology Group (ECOG) performance status** 0-1; **and**
 - Member is capable and agreeable to utilizing the device for a minimum of 18 hours per day

or
2. As a monotherapy for recurrent histologically-or radiologically-confirmed glioblastoma multiforme recurrence in the supratentorial region of the brain after receiving chemotherapy;
 - Member is an adult (defined by the FDA for this device as age 22 years or older); **and**
 - Karnofsky Performance Scale* score of 60 (70 for Medicare) or greater, or Eastern Cooperative Oncology Group (ECOG) performance status** 0-1; **and**
 - Member is capable and agreeable to utilizing the device for a minimum of 18 hours per day

NOTE:

* Karnofsky Performance Status Score:

100	Able to work. Normal; No complaints; No evidence of disease.
90	Able to work. Able to carry on normal activity; Minor symptoms.
80	Able to work. Normal activity with effort; Some symptoms.
70	Independent; not able to work. Cares for self; Unable to carry on normal activity.
60	Disabled; dependent. Requires occasional assistance; cares for most needs.
50	Moderately disabled; dependent. Requires considerable assistance and frequent care.
40	Severely disabled; dependent. Requires special care and assistance.
30	Severely disabled. Hospitalized, death not imminent.
20	Very sick. Active supportive treatment needed.
10	Moribund. Fatal processes are rapidly progressing

**** Eastern Cooperative Oncology Group (ECOG) Performance Status**

0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
2	Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours

3	Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
4	Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
5	Dead

LIMITATION: Authorization for this device will be for a period of one (1) year.

EXCLUSIONS:

The use of TTF devices to treat other malignant tumors (including but not limited to breast, lung, pancreatic, solid tumor brain metastases, ovarian and melanoma) and all other indications is considered Experimental, Investigational or Unproven and therefore, **NOT COVERED**.

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH: Tumor Treatment Fields

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

77299 Unlisted procedure, therapeutic radiology clinical treatment planning [when specified as plan for using an electrical stimulation device for TTF]

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

J8700 Temozolomide, oral, 5 mg

J9328 Injection, temozolomide, 1 mg

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:

Geisinger Technology Assessment Committee. Tumor Treatment Fields for Treatment of Glioblastoma. April 13, 2016.

ECRI Institute. Emerging Technology Evidence Report. Tumor treating fields therapy (Optune) for treating recurrent Glioblastoma. Nov. 2015

Stupp R, Tailibert S, Kanner AA, et al. maintenance therapy with tumor treating fields plus temozolomide vs temozolomide alone for glioblastoma: A randomized clinical trial. JAMA 2015;314(23):2535-2543.

Wong ET, Lok E, Swanson KD. Clininical benefit in recurrent glioblastoma from adjuvant NovoTT-100A and TCCC after temozolomide and bevacizumab failure: a preliminary observation. Cancer Medicine 2015;4(3):383-391.

Lacouture ME, Davis ME, Elzinga G, et al. Characterization and management of dermatologic adverse events with NovoTTF-100A system, a novel anti-mitotic electric field device for the treatment of recurrent glioblastoma. Seminars in Oncology 2014;41(3) Suppl 4:S1-S14.

Vymazal J, Wong ET. Response patterns of recurrent glioblastomas treated with tumor treating fields. *Seminars in Oncology* 2014;41(5)Suppl 6:S14-S24.

Kanner AA, Wong ET, Villano JL, et al. Post hoc analysis of intention-to-treat population in phase III comparison of NovoTTF-100A system versus best physician's choice chemotherapy. *Seminars in Oncology* 2014;41(5)Suppl 6:S25-S34.

Mrugala MM, Englehard HH, Tran DD, et al. Clinical practice experience with NovoTTF-100A system for glioblastoma: the patient registry dataset (PRiDe). *Seminars in Oncology* 2014;41(5)Suppl 6:S4-S13.

Kirkson ED, Gurvich Z, et al. Disruption of cancer cell replication by alternating electric fields. *Cancer Research* 2004;64:3288-3295.

Wong ET, Lok E, et al. Response assessment of NovoTTF-100A versus best physician's choice chemotherapy in recurrent glioblastoma. *Cancer Medicine* 2014;3(3):592-602.

Rehman AA, Elmore KB, Mattei TA. The effects of alternating electric fields in glioblastoma: current evidence on therapeutic mechanisms and clinical outcomes. *Neurosurgical Focus* 2015;38(3):E14.

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Central Nervous System Cancers. Version 1.2024

ECRI Institute. Emerging Technology Reports – Evidence Analysis. Tumor Treating Fields Therapy (Optune) for Recurrent Glioblastoma. July 2016.

Mittal S, Klinger NV, Michelhaugh SK, et al. Alternating electric tumor treating fields for treatment of glioblastoma: Rationale, preclinical, and clinical studies. *J Neurosurg*. 2017 Feb 24:1-8

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.

Toms SA and Tapinos N. Recent advances in the treatment of gliomas- comprehensive brain tumor center. *RI Med J* 2017 Jun1;100(6):43-46.

Mehta M, et al. Critical review of the addition of tumor treating fields (TTFields) to the existing standard of care for newly diagnosed glioblastoma patients. *Crit Rev Oncol Hematol* 2017 Mar;111:60-68.

Department of Human Services, PA Health Choices Managed Care Operations Memorandum Technology Assessment Group OPS # 05/2018-009

Taphoorn MJB, Dirven L, Kanner AA, et al.(2018) Influence of treatment with tumor-treating fields on health-related quality of life of patients with newly diagnosed glioblastoma: a secondary analysis of a randomized clinical trial. *JAMA Oncol*. 2018;4(4):495-504.

Mittal S, Klinger NV, Michelhaugh SK, et al. Alternating electric tumor treating fields for treatment of glioblastoma: Rationale, preclinical, and clinical studies. *J Neurosurg*. 2018;128(2):414-421.

Noridian Healthcare Solutions, LLC L34823 TUMOR TREATMENT FIELD Therapy (TTFT) 9/1/2019

Noridian healthcare Solutions LLC A52711 Tumor Treatment Field Therapy (TTFT) - Policy Article

Toms SA, Kim CY, Nicholas G, et al. Increased compliance with tumor treating fields therapy is prognostic for improved survival in the treatment of glioblastoma: a subgroup analysis of the EF-14 phase III trial. *J Neurooncol*. 2019 Jan;141(2):467-473

Riley, M. M., San, P., Lok, E., Swanson, K. D., Wong, E. T. The Clinical Application of Tumor Treating Fields Therapy in Glioblastoma. *J. Vis. Exp.* 2019;(146), e58937

ECRI Institute, Optune treatment kit (Novocure, Ltd.) for treating newly diagnoses glioblastoma. Health Technology Assessment Jan 2019

Armoiry X, Auguste P, et al. The cost-effectiveness of tumor-treating fields in patients with newly diagnosed glioblastoma, *Neuro-Oncology*, 2019; 21(Suppl 3):iii68–iii69

Kim CY, Paek SH, Nam DH, et al. Tumor treating fields plus temozolomide for newly diagnosed glioblastoma: a sub-group analysis of Korean patients in the EF-14 phase 3 trial. J Neurooncol. 2020 Feb;146(3):399-406.

Marenco-Hillebrand L, Wijesekera O, Suarez-Meade P, et al. Trends in glioblastoma: outcomes over time and type of intervention: a systematic evidence based analysis. J Neurooncol. 2020 Apr;147(2):297-307.

Jin L, Guo S, Zhang X, Mo Y, et al. Optimal treatment strategy for adult patients with newly diagnosed glioblastoma: a systematic review and network meta-analysis. Neurosurg Rev. 2020 Oct 10

Regev O, Merkin V, Blumenthal DT, et al. Tumor-treating fields for the treatment of glioblastoma: A systematic review and meta-analysis. Neurooncol Pract. 2021;8(4):426-440

PA Dept. of Human Services. Office of Medical Assistance Programs Technology Assessment Group Ops # 10/2023-014

Ballo MT, Conlon P, Lavy-Shahaf G, et al. Association of Tumor Treating Fields (TTFields) therapy with survival in newly diagnosed glioblastoma: a systematic review and meta-analysis. J Neurooncol. 2023;164(1):1-9.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 5/16

Revised: 7/16 (updated line of business specific coverage), 5/18 (Added Medicaid Segment); 5/19 (revised criteria); 8/19 (added Medicare coverage); 8/21 (add GBM definition)

Reviewed: 5/17, 8/20, 8/22, 8/23, 8/24

CMS UM Oversight Committee Approval: 12/23; 11/8/24

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.