MEDICAL COVERAGE POLICY	
SERVICE: Tumor Treating Fields	
Policy Number:	**226**
Effective Date:	**08/01/2020**
Last Review:	**06/25/2020**
Next Review Date:	**06/25/2021**

Important note:
Unless otherwise indicated, this policy will apply to all lines of business.
Even though this policy may indicate that a particular service or supply may be considered medically necessary and thus covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage (EOC) or Summary Plan Description (SPD) to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare-linked plan members, this policy will apply unless there are Medicare policies that provide differing coverage rules, in which case Medicare coverage rules supersede guidelines in this policy. Medicare-linked plan policies will only apply to benefits paid for under Medicare rules, and not to any other health benefit plan benefits. CMS's Coverage Issues Manual can be found on the CMS website. Similarly, for Medicaid-linked plans, the Texas Medicaid Provider Procedures Manual (TMPPM) supersedes coverage guidelines in this policy where applicable.

SERVICE: Tumor Treating Fields or Electrical Tumor Treatment Fields Therapy

PRIOR AUTHORIZATION: Required.

POLICY: Please review the plan's EOC (Evidence of Coverage) or Summary Plan Description (SPD) for coverage details.

For Medicare plans, please refer to appropriate Medicare LCD (Local Coverage Determination). If there is no applicable LCD, use the criteria set forth below.

For Medicaid plans, please confirm coverage as outlined in the Texas Medicaid TMPPM.

SWHP/FirstCare may consider devices that generate Tumor Treating Fields (TTF) or Electrical Tumor Treatment Fields (ETTF) medically necessary in the following situations:

1. Member has newly diagnosed and histologically confirmed glioblastoma multiforme (GBM), or World Health Organization grade IV astrocytoma, and has received standard surgery, radiation therapy and chemotherapy, and there is no evidence of progression by Response Assessment in Neuro-Oncology (RANO) criteria, and ETTF/TTF is begun within 7 weeks of last chemo- or radio-therapy; OR
2. Member has histologically- or radiologically-confirmed recurrent GBM limited to the supratentorial region following treatment with chemotherapy after surgical and radiation treatments have been exhausted.

… and if the following conditions are met:

1. Member is age 22+ years old, AND
2. Has a Karnofsky Performance Status (KPS) score of >70; AND
3. ETTF/TTF is used on average of 18 hours daily.

When the above criteria are met, up to 3 months of ETTF/TTF therapy may be approved.

Subsequent approval(s) for 3 months for continuation of ETTF/TTF therapy may be medically necessary if:

- There is face-to-face clinical re-evaluation by the treating practitioner; and; AND

- There is objective evidence of adherence to therapy.

Therapy with ETTF/TTF may NOT be medically necessary when any of the following are present:

- Active implanted medical device (e.g., deep brain stimulators, spinal cord stimulators, pacemakers, defibrillators), pregnancy, cranial shunts, skull defects;
- Treatment for more than 24 months;
- Treatment in the presence of other malignant tumors.

SWHP/FirstCare considers the use of a brain mapping system (e.g. NovoTAL™) medically necessary in order to optimize placement of the transducer array for maximal effectiveness of this treatment.

For **Medicare** lines of business, this therapy is covered **ONLY** for newly diagnosed glioblastoma.

OVERVIEW:

The NovoTTF-100A System, also referred to as Novocure™ or Optune®, was approved by the Food and Drug Administration (FDA) in April 2011 for treatment of recurrent GBM and was approved for an expanded indication to newly diagnosed GBM in October 2015. It's a novel device that emits alternating electric fields that disrupt the rapid cell division exhibited by cancer cells.

Alternating electric fields ha.ve been reported to have an inhibitory effect on the growth rate of a variety of tumor cells. This non-thermal effect selectively affects dividing cells while quiescent cells are left intact. There are 2 proposed modes of action for these anti-tumoric effects: (i) arrest of cell proliferation, and (ii) destruction of cells while undergoing division. Both effects can be seen when such fields are applied to cells undergoing mitosis.

MANDATES:

SUPPORTING DATA:

CODES:

Important note:
CODES: Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.

CPT	
ICD10 codes:	C71.0 - C71.9
ICD10 Not covered:	
HCPCS	E0766, A4555

CMS: LCD L34823 effective 9/1/2019.

POLICY HISTORY:

Status	Date	Action
New	01/31/2017	New policy
Reviewed	11/07/2017	Rewritten with different coverage and criteria
Reviewed	09/25/2018	Clarified coverage for recurrent and newly diagnosed tumors

Reviewed	12/19/2019	Revised criteria language and updated to align with LCD
Reviewed	06/25/2020	Added language for use across all LOBs

REFERENCES:

The following scientific references were utilized in the formulation of this medical policy. SWHP will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available and they are not included in the list, please forward the reference(s) to SWHP so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.

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2. American Association of Neuroscience Nurses (AANN). Care of the adult patient with a brain tumor. Chicago, IL: American Association of Neuroscience Nurses (AANN); 2014. Summary on National Guideline Clearinghouse [website]. Available at: http://www.guideline.gov/content.aspx?id=48105.
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8. Macdonald DR, Cascino TL, Schold SC, Cairncross JG. Response criteria for phase II studies of supratentorial malignant glioma. *J Clin Oncol*. 1990;8(7):1277-1280.
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11. Randall T. Electric Helmet Slows Brain Tumors Without Chemo Side Effects [news article]. June 5, 2010. Bloomberg Business [website]. Available at: http://www.bloomberg.com/news/articles/2010-06-05/electric-helmet-slows-brain-tumors-without-chemotherapy-s-side-effects.
12. Rodrigues G, Choy H, Bradley J, et al. Adjuvant radiation therapy in locally advanced non-small cell lung cancer: Executive summary of an American Society for Radiation Oncology (ASTRO) evidence-based clinical practice guideline. *Pract Radiat Oncol*. 2015;5(3):149-155.
13. 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.
14. Stupp R, Hegi ME, Gilbert MR, Chakravarti A. Chemoradiotherapy in malignant glioma: standard of care and future directions. *J Clin Oncol*. 2007;25(26):4127-4136.

15. 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*. 2015;314(23):2535-2543.
16. Vymazal J, Wong ET. Response patterns of recurrent glioblastomas treated with tumor-treating fields. *Semin Oncol*. 2014;(41 Suppl 6):S14-S24.
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