Important note
Even though this policy may indicate that a particular service or supply may be considered 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 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 Senior Care members, this policy will apply unless Medicare policies extend coverage beyond this Medical Policy & Criteria Statement. Senior Care 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.

SERVICE: Alternating Electrical Fields Therapy (Novocure™ or Optune®)

PRIOR AUTHORIZATION: Required.

POLICY: SWHP may consider devices that generate alternating electrical fields medically necessary to treat the following condition(s):

1. To treat members age 22 years and older, having a Karnofsky Performance Status (KPS) score of >60, with newly diagnosed, supratentorial glioblastoma in combination with temozolomide as adjunctive treatment, following initial treatments that include surgery, chemotherapy, or radiation therapy.

2. To treat members with histologically confirmed glioblastoma (World Health Organization grade IV astrocytoma) recurrences in the supratentorial region of the brain after receiving standard therapy.

When the above criteria are met, an initial 3 months of electric TTF therapy will be approved. Subsequent approval(s) for continuation of electric TTF may be medically necessary if:

- There is no documented evidence of disease progression by magnetic resonance imaging (MRI) done at a minimum of every 2-4 months. The MRI scan report will be submitted as part of any request for continuation of electric TTF treatment; AND
- Documentation that the individual and/or caregiver has been applying the device daily.

SWHP 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.

This treatment is NOT covered under Medicare lines of business. LCD L34823: “Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.”

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 have 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

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CMS: LCD L34823 effective 1/1/2017.

POLICY HISTORY:

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<td>09/25/2018</td>
<td>Clarified coverage for recurrent and newly diagnosed tumors</td>
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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.

1. NCCN Guidelines Version 1.2016, Central Nervous System Cancers
### MEDICAL COVERAGE POLICY

**SERVICE:** Alternating Electrical Fields Therapy (Novocure™ or Optune®)

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