Policy

This Medical Policy does not constitute medical advice. When deciding coverage, the enrollee’s specific plan document must be referenced. The terms of an enrollee’s plan document (Certificate of Coverage (COC) or Summary Plan Description (SPD)) may differ from this Medical Policy. In the event of a conflict, the enrollee’s specific benefit plan document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements, and the plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. Quartz reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary.

Procedure

I. Documentation Required:
   In order to facilitate the authorization process, referral requests MUST include the following:
   1. Diagnosis of supratentorial glioblastoma multiforme (GBM).
   2. History of prior treatment for GBM.
   3. Physician assessment, plan of care and order for the requested electric tumor treatment field device.
   4. Results of most recent MRI imaging prior to the request to continue therapy.

II. Criteria for Medical Necessity:
   A. Initial Rental of an Electric Tumor Treatment Field (TTF) Device
      A three (3) month rental of an FDA approved TTF device is considered medically necessary for adults ages 22 and older when EITHER of the following are met:
      a. As monotherapy for recurrent histologically confirmed GBM when BOTH of the following are met:
         i. The patient has a Karnofsky Performance Status score of 60 or higher;
            AND
         ii. The patient or caregiver is willing and able to apply and maintain the device an average of at least 18 hours per day; OR
      b. As adjunctive therapy with concomitant temozolomide for newly diagnosed, histologically confirmed GBM after tumor debulking, completion of chemotherapy and radiation therapy when BOTH of the following are met:
         i. The patient has a Karnofsky Performance Status score of 60 or higher;
            AND
         ii. The patient or caregiver is willing and able to apply and maintain the device an average of at least 18 hours per day.

   B. Continuation of Rental of an Electric Tumor Treatment Field (TTF) Device
      Continuation of rental of the TTF device will be authorized monthly, contingent upon a compliance report that documents an average of at least 18 hrs of use per day and BOTH of the following are met:
a. The patient has been evaluated by their oncologist within the last 3 months and has a Karnofsky Performance Status score of 60 or higher; **AND**  

b. Patient has no evidence of disease progression on follow-up imaging performed within the last 3 months.

### III. Indications Considered Experimental and Investigational** (Not an all-inclusive list):

1. TTF devices used for treatment of any malignant tumors other than those identified in this policy.
2. Continuation of rental for patients without updated imaging completed at least every 3 months.
3. Treatment with Electronic Tumor Treatment Fields device (Optune®) for patients that have a history of disease progression while using TTF treatment.
4. Concomitant therapy with any other chemotherapeutic or immunotherapy agent other than temozolomide for adjuvant therapy.

#### HCPCS CODES:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>A4555</td>
<td>Electrode/Transducer for use with electrical stimulation device used for cancer treatment, replacement only.</td>
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<tr>
<td>E0766</td>
<td>Electrical stimulation device, used for cancer treatment, includes all accessories, any type.</td>
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#### REFERENCES:


