Electric Tumor Treatment Fields
Policy Number: PG0371
Last Review: 05/11/2021

GUIDELINES

- This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder terms, conditions, exclusions and limitations contract. It does not constitute a contract or guarantee regarding coverage or reimbursement/payment. Self-Insured group specific policy will supersede this general policy when group supplementary plan document or individual plan decision directs otherwise.
- Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards.
- This medical policy is solely for guiding medical necessity and explaining correct procedure reporting used to assist in making coverage decisions and administering benefits.

SCOPE

X Professional
X Facility

DESCRIPTION

Electric tumor treating field (ETTF) therapy, also known as alternating electric field therapy, is a noninvasive technology treatment that uses low-intensity electrical field pulses, delivered by a portable medical device (Optune), to inhibit cell proliferation and leads to programmed cell death in the treatment of glioblastoma (GBM). GBM is a fast-growing malignant tumor of the glial tissue of the nervous system. ETTFs are created by alternating intermediate frequency (200 kilohertz [kHz]) electric currents that are delivered to a malignant tumor site via insulated electrodes placed around the region of the body containing the tumor.

POLICY

HMO, PPO, Individual Marketplace, Elite/ProMedica Medicare Plan, Advantage

Effective 07/01/2021 Prior authorization is required for electric tumor treating field devices, procedure E0766.

Non-participating providers are required to obtain prior authorization BEFORE any services are rendered.

COVERAGE CRITERIA

HMO, PPO, Individual Marketplace, Elite/ProMedica Medicare Plan, Advantage

Paramount considers the use of U.S. Food and Drug Administration (FDA)-approved electric tumor treating field (ETTF) devices (e.g. Optune) as reasonable and medically necessary for up to three months each for the treatment of newly and recurrent diagnosed Supratentorial glioblastoma (GBM) as indicated below:

The following is proven and medically necessary for treating newly diagnosed histologically-confirmed Supratentorial glioblastoma (GBM):
The use of U.S. Food and Drug Administration (FDA) approved devices to generate electric tumor treatment fields (TTF) when used according to FDA labeled indications, contraindications, warnings and precautions, and when ALL of the following criteria are met:

- Member 22 years of age or older; and
- Member has received initial treatment with maximal debulking surgery, if possible; and
- Treatment with radiation therapy has been completed; and
- Member is receiving chemotherapy drug Temozolomide (TMZ) as the only cancer drug; and
- Member has a Karnofsky Performance Status (KPS) score of ≥ 60 or Eastern Cooperative Oncology Group (ECOG) Performance Status ≤ 2; and
- Member and caregiver has been counselled and trained on application and that the device must be worn at least 18 hours daily

Subsequent approval(s) for continuation of electric TTF treatment is based on:

- Magnetic resonance imaging (MRI) scan has been performed ≤ 2 months prior to request and documents no evidence of disease progression; and
- KPS score of ≥ 60 or ECOG Performance Status ≤ 2; and
- Documentation that the individual has been using the device at least 18 hours daily

The following is proven and medically necessary for treating radiologically confirmed recurrence of GBM in the Supratentorial region of the brain:

- The use of FDA approved devices to generate electric TTF after initial chemotherapy when used according to FDA labeled indications, contraindications, warnings and precautions and when ALL of the following criteria are met:
  - Member 22 years of age or older; and
  - The device is used as a monotherapy treatment after failure of standard medical therapy (e.g., chemotherapy, surgery, and/or radiation therapy); and
  - Member has a KPS score of ≥ 60 or ECOG Performance Status ≤ 2; and
  - Device data recording confirms compliance of usage for an average of 18 hours per day.

When all of the above criteria are met for either newly diagnosed or recurrent GBM, an initial 3 months of electric TTF therapy will be approved.

NON-COVERAGE Electric Tumor Treatment Fields is considered investigational for all other indications, including, but not limited to:

- A request is for an additional 90 days of therapy and there has been no disease progression in the last 90 days of TTF therapy.
- If the following contraindications are present:
  - Active implanted medical device (eg, deep brain stimulators, spinal cord stimulators, vagus nerve stimulators, pacemakers, defibrillators, or programmable shunts); OR
  - Bullet fragments; OR
  - Known sensitivity to conductive hydrogels (eg, gels used on electrocardiogram [ECG] stickers or transcutaneous electrical nerve stimulation [TENS] electrodes); OR
  - Pregnancy; OR
  - Shunts; OR
  - Skull defects (eg, missing bone with no replacement); OR
  - If utilized as monotherapy (ie, without Temozolomide) for newly diagnosed GBM; OR
  - Treatment greater than 24 months; OR
  - Treatment of malignant pleural mesothelioma; OR
  - Treatment of other malignant tumors other than GBM (eg, breast, lung, pancreas)
  - Use of electric TTF therapy with concurrent medical therapy (e.g., bevacizumab or chemotherapy) for treatment of recurrent GBM
- Computer mapping software (NovaTal) for planning TTF therapy is experimental/investigational for all indications, as there is insufficient evidence to establish the efficacy of these products in the long-term outcomes of patients receiving TTF therapy.
The Optune was approved by the United States Food and Drug Administration (FDA) in April 2011, to deliver TTF therapy to adult patients (aged 22 years or older) with confirmed GBM, following confirmed recurrence in an upper region of the brain (supratentorial) after receiving chemotherapy. The device is intended to be used as a standalone treatment, as an alternative to standard medical therapy for recurrent GBM after surgical and radiation options have been exhausted.

The Optune was approved by the FDA in October 2015 to deliver TTF therapy to adult patients (aged 22 years or older) with newly-diagnosed GBM. The device is intended to be given along with the chemotherapy drug temozolomide, following standard treatments that include surgery, and radiation therapy and chemotherapy used together.

**CODING/BILLING INFORMATION**

The inclusion or exclusion of a code in this section does not necessarily indicate coverage. Codes referenced in this clinical policy are for informational purposes only. Codes that are covered may have selection criteria that must be met.

Payment for supplies may be included in payment for other services rendered.

<table>
<thead>
<tr>
<th>CPT CODE</th>
<th>Description</th>
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<tbody>
<tr>
<td>64999</td>
<td>Unlisted procedure, nervous system (Not Covered if used to report any procedure outlined in Non-Coverage section)</td>
</tr>
<tr>
<td>77299</td>
<td>Unlisted procedure, therapeutic radiology clinical treatment planning (Not Covered if used to report any procedure outlined in Non-Coverage section)</td>
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<tr>
<td>A4555</td>
<td>Electrode/transducer for use with electrical stimulation device used for cancer treatment, replacement only (Always considered integral to the rental of the electrical stimulation device and not separately reimbursable)</td>
</tr>
<tr>
<td>E0766</td>
<td>Electrical stimulation device used for cancer treatment, includes all accessories, any type</td>
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Paramount reserves the right to review and revise our policies periodically when necessary. When there is an update, we will publish the most current policy to https://www.paramounthealthcare.com/services/providers/medical-policies/.

**Revision History Explanation**

**Original Effective Date: 05/27/2016**

<table>
<thead>
<tr>
<th>Date</th>
<th>Explanation &amp; Changes</th>
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<tbody>
<tr>
<td>05/27/16</td>
<td>• Policy created to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)</td>
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| 08/25/17 | • Tumor treatment field therapy (E0766) is now covered with prior authorization for all product lines  
          • Treatment planning software (i.e., NovoTAL) for use with TTF therapy for any indication is non-covered for all product lines  
          • Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG). |
| 08/23/18 | • Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG) |
| 09/27/18 | • Treatment planning software (i.e., NovoTAL) for use with TTF therapy is now covered with prior authorization for all product lines  
          • Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG) |
| 10/25/18 | • Tumor treatment field (TTF) therapy (i.e., Optune) (E0766) and treatment planning software (i.e., NovoTAL) for use with TTF therapy are non-covered for all product lines per administrative direction to follow CMS and ODM guidelines  
          • Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG) |
| 01/2020  | • Policy removed from the Internet, January 2020                                      |
| 05/21/2021 | • Policy title changed from Tumor Treatment Field Therapy for Glioblastoma to Electric Tumor Treatment Fields  
              • Coverage Criteria indicated (changed from noncoverage)  
              • Effective 07/01/2021 Prior authorization is required for electric tumor treating field devices, procedure E0766. |

**References/Resources**

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services

Ohio Department of Medicaid

American Medical Association, Current Procedural Terminology (CPT®) and associated publications and services

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets

Hayes, Inc.

Industry Standard Review

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