**Medical Necessity Guidelines: Tumor Treating Fields**

*Effective: August 1, 2023*

<table>
<thead>
<tr>
<th>Prior Authorization Required</th>
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<tbody>
<tr>
<td>If REQUIRED, submit supporting clinical documentation pertinent to service request.</td>
</tr>
<tr>
<td>Yes ☒ No ☐</td>
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<tr>
<th>Notification Required</th>
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<tbody>
<tr>
<td>IF REQUIRED, concurrent review may apply</td>
</tr>
<tr>
<td>Yes ☐ No ☒</td>
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### Applies to:

#### Commercial Products
- ☒ Harvard Pilgrim Health Care Commercial products; 800-232-0816
- ☒ Tufts Health Plan Commercial products; 617-972-9409
  - CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

#### Public Plans Products
- ☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); 888-415-9055
- ☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; 888-415-9055
- ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; 857-304-6404
- ☒ Tufts Health Unify* – OneCare Plan (a dual-eligible product); 857-304-6304

*The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.

#### Senior Products
- ☐ Harvard Pilgrim Health Care Stride Medicare Advantage; 866-874-0857
- ☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); 617-673-0965
- ☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); 617-673-0965
- ☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); 617-673-0965

**Note:** While you may not be the provider responsible for obtaining prior authorization or notifying Point32Health, as a condition of payment you will need to ensure that any necessary prior authorization has been obtained and/or Point32Health has received proper notification. If notification is required, providers may additionally be required to provide updated clinical information to qualify for continued service.

### Overview

Glioblastomas (grade IV astrocytomas) are one of the most common types of primary malignant brain tumors in adults. These tumors develop from glial cells in the brain and are usually highly malignant (cancerous) because the cells reproduce quickly, and they are supported by a large network of blood vessels. The overall prognosis is poor, even with the best standard of care. Currently, the standard of care for glioblastoma multiforme (GBM) includes debulking surgery, combination treatment with radiotherapy and Temozolomide (TMZ) chemotherapy, and adjuvant chemotherapy with TMZ. With optimal treatment, the median survival time is approximately 10 to 14 months. Only approximately one third of patients survive for one year following diagnosis of GBM, and fewer than 5% live beyond 5 years. Virtually all patients with newly diagnosed GBM relapse despite best available treatment. Patients with recurrent GBM have a median survival time of five to seven months.

Malignant mesothelioma is a rare neoplasm that arises most commonly from the mesothelial surfaces of the pleural cavity, less commonly from the peritoneal surface, and extremely rarely from the tunica vaginalis or pericardium. It often has an extremely poor prognosis; the median survival is 4 to 13 months for untreated patients and 6 to 18 months for treated patients, regardless of the therapeutic approach.

Tumor treating fields (TTF) therapy utilizes mild electrical field pulses to inhibit tumor cell proliferation and/or destroy tumor cells. TTF aims to disrupt the rapid cell division exhibited by malignant cells. TTF have not been shown to have an effect on cells that are not undergoing division.
The Optune-lua system produces tumor treating fields within the human body through transducer arrays placed on surface of scalp or chest.

**Clinical Guideline Coverage Criteria**

The Plan considers the use of U.S. Food and Drug Administration (FDA) approved tumor treating fields (TTF) device (e.g., Optune-lua) medically necessary documentation confirms ALL the following:

1. Newly diagnosed supratentorial glioblastoma following both debulking surgery and radiation therapy with concomitant chemotherapy and **ALL** of the following are met:
   a. TTF is in combination with temozolomide (TMZ); **and**
   b. Member is 22 years of age or older; **and**
   c. Member has the ability to use the device for an average of 18 hours each day; **and**
   d. Member has Karnofsky score > 70 or Eastern Cooperative Oncology Group (ECOG) performance status 0-1 **OR**

2. TTF as monotherapy in member with histologically or radiologically confirmed recurrent glioblastoma (GBM) in the supratentorial region of the brain after receiving chemotherapy and **ALL** the following are met:
   a. Surgical and radiation options have been exhausted; **and**
   b. Member is 22 years of age or older; **and**
   c. Member has the ability to use the device for an average of 18 hours each day. **OR**

3. Adult member with unresectable, locally advanced or metastatic, malignant pleural mesothelioma (MPM) when used concurrently with pemetrexed and platinum-based chemotherapy

**Note:** Authorization will be in 3-month increments

**Limitations**

The use of tumor treating field (TTF) devices for all other indications as this is considered experimental and investigational.

**Supporting Information**

**Eastern Cooperative Oncology Group (ECOG) performance status**

<table>
<thead>
<tr>
<th>Grade</th>
<th>ECOG Performance Status</th>
</tr>
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<tbody>
<tr>
<td>0</td>
<td>Fully active, able to carry on all pre-disease performance without restriction</td>
</tr>
<tr>
<td>1</td>
<td>Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work</td>
</tr>
<tr>
<td>2</td>
<td>Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours</td>
</tr>
<tr>
<td>3</td>
<td>Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours</td>
</tr>
<tr>
<td>4</td>
<td>Completely disabled; cannot carry on any selfcare; totally confined to bed or chair</td>
</tr>
<tr>
<td>5</td>
<td>Dead</td>
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<table>
<thead>
<tr>
<th>Karnofsky Performance Status Scale</th>
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<tbody>
<tr>
<td><strong>Condition</strong></td>
</tr>
<tr>
<td>----------------</td>
</tr>
<tr>
<td>Able to carry on normal activity and to work; no special care needed</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
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<tr>
<td>Unable to work; able to live at home and care for most personal needs; varying amount of assistance needed</td>
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</table>
### Condition | Value (%) | Level of Functional Capacity
--- | --- | ---
Unable to care for self; requires equivalent of institutional or hospital care; diseases may be progressing rapidly | 50% | Requires considerable assistance and frequent medical care
| 40% | Disabled; requires special care and assistance
| 30% | Severely disabled; hospital admission indicated although death not imminent
| 20% | Very sick; hospital admission necessary; active supportive treatment necessary
| 10% | Moribund; fatal processes progressing rapidly
| 0% | Dead

### Codes

The following code(s) require prior authorization:

**Table 1: CPT/HCPCS Codes**

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

### References:

5. Tumor Treating Fields (Optune) for Treatment of Glioblastoma. Hayesinc.com/subscribers [via subscription only]. Accessed October 26, 2021
**Approval And Revision History**

October 21, 2020: Reviewed by the Medical Policy Approval Committee (MPAC), renewed without changes

Subsequent endorsement date(s) and changes made:
- November 4, 2020: Fax number for Unify updated
- November 17, 2021: Reviewed at IMPAC. Effective March 1, 2022, criteria and coding updated for Point32Health integration purposes.
- December 21, 2022: Reviewed by MPAC, renewed without changes
- June 21, 2023: Reviewed by MPAC. Added coverage criteria for mesothelioma, effective August 1, 2023

**Background, Product and Disclaimer Information**

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.