Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines:

Tumor Treating Fields

Effective: August 1, 2023

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	Yes ☒ No ☐
Notification Required IF REQUIRED, concurrent review may apply	Yes ☐ No ☒

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 the 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

Grade	ECOG Performance Status
0	Fully active, able to carry on all pre-disease performance without restriction
1	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
2	Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours
3	Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours
4	Completely disabled; cannot carry on any selfcare; totally confined to bed or chair
5	Dead

Karnofsky Performance Status Scale

Condition	Value (%)	Level of Functional Capacity
Able to carry on normal activity and to work; no special care needed	100%	No complaints; no evidence of disease
	90%	Able to carry on normal activity; minor signs or symptoms of disease
	80%	Normal activity with effort; some signs or symptoms of disease
Unable to work; able to live at home and care for most personal needs; varying amount of assistance needed	70%	Cares for self; unable to carry on normal activity or to do active work
	60%	Requires occasional assistance but is able to are for most personal needs

Condition	Value (%)	Level of Functional Capacity
	50%	Requires considerable assistance and frequent medical care
Unable to care for self; requires equivalent of institutional or hospital care; diseases may be progressing rapidly	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

Code	Description
E0766	Electrical stimulation device used for cancer treatment, includes all accessories, any type
A4555	Electrode/transducer for use with electrical stimulation device used for cancer treatment, replacement only

References:

1. United States Food and Drug Administration. Summary of Safety and Effectiveness Data, Novo TTF-100A System (Premarket Approval Number P100034). Available at fda.gov. Accessed October 26, 2021..
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3. Optune Treatment Kit (Novocure, Ltd.) for Treating Newly Diagnosed Glioblastoma. ECRI.org/login [via subscription only]. Accessed October 26, 2021.
4. Optune Treatment Kit (Novocure, Ltd.) for Treating Recurrent Glioblastoma. ECRI.org/login [via subscription only]. Accessed October 26, 2021.
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6. Local Coverage Determination (LCD): Tumor Treatment Field Therapy (TTFT) (L34823). Accessed June 15, 2023. LCD - Tumor Treatment Field Therapy (TTFT) (L34823) (cms.gov)
7. Initial treatment and prognosis of newly diagnosed glioblastoma in adults. https://www.uptodate.com/contents/initial-treatment-and-prognosis-of-newly-diagnosed-glioblastoma-in adults?search=optune%20tumor%20treatment&source=search_result&selectedTitle=1~6&usage_type=default&display_rank=1 (via subscription only). Accessed October 26, 2021.
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9. ECOG performance status. https://ecog-acrin.org/resources/ecog-performance-status. Accessed October 26. 2021.
10. Survival estimates in advanced terminal cancer. https://www.uptodate.com/contents/survival-estimates-in-advanced-terminal-cancer?search=karnofsky&source=search_result&selectedTitle=1~67&usage_type=default&display_rank=1 (via subscription only). Accessed October 26, 2021.
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12. NovoTTF-100L System. United States Prescribing Information. US National Library of Medicine. Accessed June 14, 2023. https://www.fda.gov/medical-devices/recently-approved-devices/novottftm-100l-system-h180002
13. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Mesothelioma: Pleural. Accessed June 15, 2023. meso_pleural.pdf (nccn.org)

14. Tsao AS, MD. Systemic treatment for unresectable malignant pleural mesothelioma. Accessed June 14, 2023 by subscription only. Systemic treatment for unresectable malignant pleural mesothelioma - UpToDate

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, 2021: Reviewed at Medical Policy Approval Committee (MPAC). Point32Health integrated policy approved for effective date March 1, 2022.
- 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.