Geisinger

Geisinger Health Plan Policies and Procedure Manual

Policy: MP306

Section: Medical Benefit Policy

Subject: Tumor Treatment Fields

Applicable Lines of Business

Commercial	**X**	**CHIP**	**X**
Medicare	**X**	**ACA**	**X**
Medicaid	**X**		

I. Policy: Tumor Treatment Fields

II. Purpose/Objective:

To provide a policy of coverage regarding Tumor Treatment Fields

III. Responsibility:

A. Medical Directors
B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community.
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.

- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Tumor Treating Fields, or TTF are low intensity, alternating electric fields within the intermediate frequency range. TTF disrupts cell division through physical interactions with key molecules during mitosis. TTF are generated via pairs of transducer arrays placed directly on the skin's surface in the region surrounding the tumor. The Optune™ delivery system is portable and is designed to allow individuals to continue their daily activities while receiving treatment. This non-invasive treatment is intended as a treatment for adults with histologically-confirmed glioblastoma multiforme (GBM). GBM includes: giant cell glioblastoma, gliosarcoma and epithelioid glioblastoma.

INDICATIONS: <u>REQUIRES PRIOR AUTHORIZATION BY A PLAN MEDICAL DIRECTOR OR DESIGNEE</u>

<u>COMMERCIAL AND MEDICARE BUSINESS SEGMENTS:</u>

<u>ALL Durable Medical Equipment provided for home use requires advanced determination of coverage. Devices furnished at inpatient or outpatient centers are NOT SEPARATELY REIMBURSABLE.</u>

The Optune™tumor treatment field delivery system may be considered medically necessary when **all of the following** criteria are met:

1. As concomitant therapy with temzolomide in newly diagnosed, supratentorial glioblastoma multiforme following maximal debulking surgery and completion of radiation therapy; **and**
   - Member is an adult (defined by the FDA for this device as age 22 years or older); **and**
   - Karnofsky Performance Scale* score of 60 (70 for Medicare) or greater, or Eastern Cooperative Oncology Group (ECOG) performance status** 0-1; **and**
   - Member is capable and agreeable to utilizing the device for a minimum of 18 hours per day

or

2. As a monotherapy for recurrent histologically-or radiologically-confirmed glioblastoma multiforme recurrence in the supratentorial region of the brain after receiving chemotherapy;
   - Member is an adult (defined by the FDA for this device as age 22 years or older); **and**
   - Karnofsky Performance Scale* score of 60 (70 for Medicare) or greater, or Eastern Cooperative Oncology Group (ECOG) performance status** 0-1; **and**
   - Member is capable and agreeable to utilizing the device for a minimum of 18 hours per day

NOTE:

***** Karnofsky Performance Status Score:

100	Able to work. Normal; No complaints; No evidence of disease.
90	Able to work. Able to carry on normal activity; Minor symptoms.
80	Able to work. Normal activity with effort; Some symptoms.
70	Independent; not able to work. Cares for self; Unable to carry on normal activity.
60	Disabled; dependent. Requires occasional assistance; cares for most needs.
50	Moderately disabled; dependent. Requires considerable assistance and frequent care.
40	Severely disabled; dependent. Requires special care and assistance.
30	Severely disabled. Hospitalized, death not imminent.
20	Very sick. Active supportive treatment needed.
10	Moribund. Fatal processes are rapidly progressing

**** Eastern Cooperative Oncology Group (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 house work, office work
2	Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours

3	Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
4	Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
5	Dead

LIMITATION: Authorization for this device will be for a period of one (1) year.

EXCLUSIONS:
The use of TTF devices to treat other malignant tumors (including but not limited to breast, lung, pancreatic, solid tumor brain metastases, ovarian and melanoma) and all other indications is considered Experimental, Investigational or Unproven and therefore, **NOT COVERED**.

Medicaid Business Segment:
Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH: Tumor Treatment Fields
The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov ***or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.***

77299 Unlisted procedure, therapeutic radiology clinical treatment planning [when specified as plan for using an electrical stimulation device for TTF]

A4555 Electrode/transducer for use with electrical stimulation device used for cancer treatment, replacement only
E0766 Electrical stimulation device used for cancer treatment, includes all accessories, any type
J8700 Temozolomide, oral, 5 mg
J9328 Injection, temozolomide, 1 mg

LINE OF BUSINESS:
Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

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This policy will be revised as necessary and reviewed no less than annually.

Devised: 5/16

Revised: 7/16 (updated line of business specific coverage), 5/18 (Added Medicaid Segment); 5/19 (revised criteria); 8/19 (added Medicare coverage); 8/21 (add GBM definition)

Reviewed: 5/17, 8/20, 8/22, 8/23