n05676

Tumor Treatment Field Therapy (TTF) – Medical Policy

Values

Accountability ● Integrity ● Service Excellence ● Innovation ● Collaboration

Abstract Purpose:

Network Health Plan/Network Health Insurance Corporation/Network Health Administrative Services, LLC's (NHP/NHIC/NHAS) Utilization Management (UM) department, applies review guidelines for determinations involving medical necessity of Tumor Treatment Field Therapy (TTF) (i.e. Optune Device) treatments. NHIC follows Medicare's National/Local (Wisconsin area) Coverage Determinations for its Medicare Advantage membership. This medical policy applies to NHP/NHAS commercial lines of business.

Policy Detail:

Refer to the appropriate Certificate of Coverage, Evidence of Coverage, Summary Plan Description, or Individual and Family Plan to determine eligibility and coverage because Employer Group/Plan Sponsor and government contracts may vary.

Procedure Detail:

I. Description

A. Tumor Treatment Field (TTF) is electrical therapy delivered by a portable device that creates alternating low-intensity, intermediate-frequency electric fields that inhibit cell mitosis, interfering with cell division and organelle assembly for individuals with histologically confirmed glioblastoma multiforme (GBM). The treatment involves delivering alternating electrical field therapy through 4 adhesive patches, called transducer arrays, applied to the scalp and powered through the connection cable and box, which is powered by a battery. The objective is to provide continuous action against disease progression by delivering Tumor Treatment Fields to selectively disrupt mitosis in dividing cancer cells. Treatment protocol includes 18 hours of use per day for a minimal treatment time span of 4 weeks. Evidence suggests that TTF therapy results in overall survival and progression-free survival at least equivalent to chemotherapy in individuals with recurrent GBM and increased overall survival and progression-free survival in individuals with newly diagnosed GBM compared to Temozolomide (TMZ) alone.

II. Medical Indications/Criteria

A. Network Health Plan considers TTF (i.e. Optune) medically necessary for individuals with the presence of histologically confirmed (World Health Organization grade IV astrocytoma), Glioblastoma Multiforme (GBM) when

one of the following criteria have been met:

1. For adjuvant therapy with Temozolomide (TMZ) in members with newly diagnosed GBM, limited to the supratentorial region, following maximal debulking surgery (when feasible), completion of radiation therapy together with standard of care chemotherapy, with no evidence of progression, and TTF therapy is initiated within 7 weeks from the last dose of concomitant chemotherapy or radiotherapy.
2. Monotherapy for member's diagnosed, histologically or radiologically confirmed, recurrent GBM limited to the supratentorial region following treatment with chemotherapy after surgical and radiation treatments have been exhausted.

B. Additionally, all the following criteria must be met:

1. 22 years of age or older, **AND**
2. Documentation that the member or caregiver has been trained and is able to apply and maintain the device for greater than or equal to 18 hours per day, **AND**
3. Karnofsky Performance Scale (KPS) score greater than or equal to 60%.

When **all** the above criteria are met for either newly diagnosed GBM or recurrent GBM, an initial three (3) months of TTF (Optune) will be approved.

C. Continued coverage for Tumor Treatment Fields (Optune) beyond the first three (3) months of therapy is considered medically necessary when:

1. No sooner than the 60th day but no later than the 91st day after initiating therapy, the treating practitioner must conduct a clinical re-evaluation and document that the member is continuing to use and is benefiting from TTF. Clinical documentation must include:
2. In-person clinical re-evaluation by the treating practitioner, **AND**
3. Objective evidence of adherence to therapy, reviewed by the treating practitioner. (Adherence to therapy is defined as use of TTF for an average of 18 hours per day, excluding days the treating practitioner has documented a medical need to limit or interrupt treatment).
    a. If re-evaluation does not occur until after the 91st day, but the evaluation demonstrates the member is benefiting from TTF as defined by the above criteria, continued coverage of TTF will commence with the date of the re-evaluation.
    b. Review for continued coverage of TTF will be re-evaluated every three (3) months for continued coverage.

III. Coverage

A. NHP/NHIC/NHAS may extend coverage for Tumor Treating Field Therapy for a member receiving care for GBM at a National Cancer Institute-designated Cancer Center, National Cancer Institute-designated Comprehensive Cancer Center, or National Cancer Institute-designated Cancer Research Network Facility.

B. NHIC follows CMS National Coverage Determinations (NCD) and Local Coverage Determinations (LCD) for application to its Medicare Advantage membership.

C. NHP/NHIC/NHAS may continue to extend coverage for Tumor Treatment Field Therapy for a member receiving care for GBM, when further treatment is recommended by the managing provider or practitioner, for members who continue to meet criteria for Tumor Treatment Fields (Optune) beyond the first

(3) months of therapy.

IV. Limitations/Exclusions
   A. The use of TTF (Optune) device is contraindicated and will be denied as experimental/investigational as the safety and/or effectiveness of treatment is not supported in peer reviewed literature in members who:
      1. have an implanted medical device (such as a programmable shunt, deep brain stimulation system, or implantable defibrillator), skull defect (missing bone without replacement), or bullet fragment or metal within the brain, **OR**
      2. have known sensitivity to conductive hydrogel, **OR**
      3. are pregnant.
   B. TTF (Optune) is considered experimental/investigational for all other indications as there is insufficient available published peer-reviewed literature found to establish the safety and/or effectiveness of this treatment.

V. References

   A. Centers for Medicare & Medicaid Services: Local Coverage Determination (LCD): Tumor Treatment Field Therapy (TTFT) (L34823) 1/1/2020
   B. MCG Ambulatory Care 27th edition Guidelines, Alternating Electric Field Therapy A-0930 (AC)
   C. NCCN Guidelines Version 1.2023 March 24,2023: Central Nervous System Cancers: Adult Glioma (Glio-A 4 & 5 of 8)

Regulatory Citations:

UM2

Related Documents:

Centers for Medicare & Medicaid Services: Local Coverage Determination (LCD): Tumor Treatment Field Therapy (TTFT) (L34823) 1/1/2020

HCPCS Code:*

E0766	Electrical stimulation device used for cancer treatment
A4555	Electrode/Transducer for use with Electrical Stimulation Device used for Cancer Treatment, Replacement Only
	*CPT codes are subject to change as codes are retired or new ones developed

Disclaimer:

Contract language as well as state and federal laws take precedence over any medical policy. Network Health coverage documents (i.e. Certificate of Coverage, Evidence of Coverage, Summary Plan Descriptions) outline contractual terms of the applicable benefit plan for each line of business and will be considered first in determining eligibility. Not all Network Health coverage documents are the same. Coverage may differ. Our Medicare membership follows applicable Centers for Medicare and Medicaid Services (CMS) coverage statements including National Coverage Determinations (NCD) and Local Coverage Determinations (LCD). Please refer to the CMS website at www.cms.gov.

Network Health reserves the right to review and update our medical policies on occasion as medical technologies are constantly evolving. The documentation of any brand name of a test,

product and/or procedure in a medical policy is in no way an endorsement of that product; it is for reference only.

Network Health's medical policies are for guidance and not intended to prevent the judgment of the reviewing medical director(s) nor dictate to health care providers how to practice medicine.

Origination Date: 05/10/2020	**Approval Date:** 04/18/2024	**Next Review Date:** 04/18/2025
Regulatory Body: NCQA	**Approving Committee:** Medical Policy Committee	**Policy Entity:** NHAS,NHIC,NHP
Policy Owner: Tori Kirby	**Department of Ownership:** Utilization Management	**Revision Number:** 5
Revision Reason: 06/17/2020-new policy 06/17/2021-annual review, grammar & formatting updates, CPT codes added 06/16/2022 - annual review, grammar & formatting updates, references updated, CPT code added (MPC approved 6/16/22) Approved by Medical Policy Committee on 06/16/2022 6/21/2023-annual review – consent agenda, coverage guidance expanded to include continuous coverage for members for which continued treatment is recommended and who continue to meet continued use criteria, references updated. Approved at Medical Policy Committee on 06/15/2023 04/18/2024 annual review, grammar and formatting updates, references updated		

NETWORK HEALTH PLAN/NETWORK HEALTH INSURANCE CORPORATION
MEDICAL POLICY DEVELOPMENT/REVIEW SUMMARY

1570 Midway Pl.
Menasha, WI 54952

Meeting: Utilization Management Committee	Date: 4/18/2024
Title/Topic: Medical Policy – Specialized Manual Wheelchair Bases	Policy Number: n05652
Purpose: Annual Review	Outcome: Accept with changes as outlined
Line of Business: Commercial and Medicare	Effective Date: 4/18/2024

INTRODUCTION:
Includes definition of problem or opportunity. Provides background information on the topic. Describes current state. May also include prior state and/or factors that have changed. Includes operational definitions where key terms may have varied interpretation.

Mobility assistance may be required for a variety of reasons and for varying lengths of time. The etiology of the condition requiring mobility assistance may be due to a congenital cause, injury, or disease process. Some individuals may need mobility assistance on a short-term basis, while others with chronic conditions or enduring disabilities may require mobility assistance permanently. There are a variety of mobility assistive devices widely used and available. This policy addresses Network Health's medical necessity reasons for specialized manual wheelchairs.

This medical policy provides guidance for Utilization Management Coordinator Registered Nurses (UMC-RN) regarding determinations involving the medical necessity of specialized manual wheelchair bases. This policy is due for annual review.

ACTION RECOMMENDED:
States recommendations in specific terms. Includes a summary of what should be accomplished, methods, and timetable (if applicable). Recommendations on implementation and follow-up plans may also be included.

Annual review has been conducted and the Specialized Manual Wheelchair Bases medical policy is presented for review and approval as written.

ANALYSIS/JUSTIFICATION:
Includes information relevant to the recommended action including information used in formulation the recommendations. Information will include reference to any existing Centers for Medicare & Medicaid Services (CMS) coverage determinations as well as any existing established vendor criteria. Information may include financial/cost data, service measures, projections or other key measures or process tools, recommendations from a clinical provider with expertise regarding the topic, and/or information from other widely used treatment guidelines or peer reviewed clinical literature.

Centers for Medicare and Medicaid Services(CMS) have both an NCD Determination for Mobility Assistive Equipment 280.3 and Local Coverage Determination for Manual Wheelchair Bases L33788. These documents provide criteria for basic wheelchair bases but do not provider criteria for additional bases such as roll about chairs or specialty strollers.

MAC Ambulatory Care Guideline 28th edition, Wheelchair, manual ACG: A-0354(AC) provide criteria for basic wheelchair bases but does not provide criteria for additional bases such as Roll about chairs or specialty strollers.

REFERENCES:
Includes detailed description regarding source(s) of information used for development of policy or recommendations via citation.

- CMS, Local Coverage Determination (LCD) for Manual Wheelchair Bases (L33788)
- CMS, National Coverage Determination for Mobility Assistive Equipment (MAE) (280.3), Implementation date 7/05/2005.
- MCG Ambulatory Care Guidelines 28th Edition, Wheelchairs, manual. ACG: A-0354 (AC)

REVISION REASION:
Includes the date changes or updates were made and summary of changes applied.

04/18/2024 annual review, grammar and formatting updates, references updated

Network Health reserves the right to review and update our medical policies on occasion as medical technologies are constantly evolving. The documentation of any brand name of a test, product and/or procedure in a medical policy is in no way an endorsement of that product; it is for reference only.

Network Health's medical policies are for guidance and not intended to prevent the judgment of the reviewing medical director(s) nor dictate to health care providers how to practice medicine.