

Tumor Treatment Field Therapy

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[↪ Terms and Conditions](#)

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<p>Related Medicare Advantage Policy Guideline</p> <ul style="list-style-type: none"> Durable Medical Equipment Reference List (NCD 280.1)
<p>Related Medicare Advantage Coverage Summary</p> <ul style="list-style-type: none"> Radiologic Therapeutic Procedures

Policy Summary

[↪ See Purpose](#)

Overview

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this policy guideline, the "reasonable and necessary" criteria, based on [Social Security Act § 1862\(a\)\(1\)\(A\)](#) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

Glioblastoma, also known as glioblastoma multiforme (GBM) is an aggressive type of brain cancer. It is rare, with an incidence of 3.21 cases per 100,000 population per year in the US.

Tumor Treatment Field Therapy (TTFT) uses alternating electric fields to target cancer cells. Alternating electric fields are produced by a pulse generator and transmitted by ceramic transducers placed on a patient's head. The electric fields reportedly attract and repel charged proteins during cancer cell division. Cellular proteins, because they are highly polarized, are presumed to be prevented from moving to their correct locations thus disrupting cancer cell division.

Guidelines

Initial Coverage for Newly Diagnosed Glioblastoma Multiforme

Effective for DOS on or after 09/01/2019, Tumor treatment field therapy (E0766) is covered for the treatment of newly diagnosed Glioblastoma Multiforme (GBM) only when all of the following criteria are met:

- The beneficiary has histologically confirmed (World Health Organization (WHO) grade IV astrocytoma), newly diagnosed, supratentorial GBM; and,
- The beneficiary has received initial treatment with maximal debulking surgery (when feasible), followed by chemotherapy and radiotherapy; and,
- Tumor treatment field therapy is initiated within 7 weeks from the last dose of concomitant chemotherapy or radiotherapy, whichever is later; and,
- The beneficiary has no evidence of progression by Response Assessment in Neuro-Oncology (RANO) criteria; and,
- The beneficiary has a Karnofsky Performance Score (KPS) of at least 70; and,
- The beneficiary will use TTFT for an average of 18 hours per day.

If all of the coverage criteria above are not met, claims for code E0766 will be denied as not reasonable and necessary.

Continued Coverage for Newly Diagnosed GBM Beyond the First Three Months of Therapy

Continued coverage of TTFT (E0766) beyond the first three months of therapy requires that 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 beneficiary is continuing to use and is benefiting from TTFT.

Documentation of clinical benefit is demonstrated by:

1. In-person clinical re-evaluation by the treating practitioner; and,
2. Objective evidence of adherence to therapy, reviewed by the treating practitioner.

Adherence to therapy is defined as the use of TTFT for an average of 18 hours per day (excluding days the treating practitioner has documented a medical need to limit or interrupt treatment).

If the above criteria are not met, continued coverage of TTFT will be denied as not reasonable and necessary.

If the practitioner re-evaluation does not occur until after the 91st day but the evaluation demonstrates that the beneficiary is benefiting from TTFT as defined in criteria 1 and 2 above, continued coverage of TTFT will commence with the date of that re-evaluation.

Recurrent GBM

Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary for the treatment of recurrent GBM.

Other Uses

The use of TTFT for any indications other than newly diagnosed GBM will be denied as not reasonable and necessary.

Coding Guidelines

Code E0766 describes devices that generate electromagnetic fields utilized in the treatment of cancer. The electromagnetic energy generated is transmitted to the body by means of surface electrodes or transducers. This code is inclusive of all associated supplies necessary for the effective use of code E0766 including, but not limited to, transducers/surface electrodes, lead wires, adhesive patches, connectors, conductive gel and skin preps.

Code A4555 is not valid for billing to Medicare. If code A4555 is billed, it will be denied as an invalid code.

Policy Specific Documentation Requirements

Devices coded E0766 are classified by the Food & Drug Administration as Class III devices; therefore, all claims for code E0766 must include the KF modifier.

Initial Coverage (First Three Months)

On claims for the first through third months, suppliers must add a KX modifier to code E0766 only if all of the criteria has been met.

Continued Coverage Beyond the First Three Months of Therapy

On the fourth month's claim (and any month thereafter), the supplier must add a KX modifier to code E0766 only if both the "Initial Coverage" criteria and the "Continued Coverage" criteria have been met.

If the supplier does not obtain information from the practitioner that the beneficiary has demonstrated benefit from the use of, and is adhering to, TTFT treatment in time for submission of the fourth or succeeding months' claims, the supplier may still submit the claims, but a KX modifier must not be added.

If the supplier chooses to hold claims for the fourth and succeeding months pending receipt of information from the treating practitioner that the beneficiary received a clinical re-evaluation between the 60th and 91st day, had documented benefit from the use of, and is adhering to, TTFT treatment, those claims may then be submitted with the KX modifier.

If the supplier chooses to hold claims for the fourth and succeeding month pending receipt of information from the treating practitioner but learns that the beneficiary did not receive a clinical re-evaluation between the 60th and 91st day but rather was re-evaluated at a later date and had documented benefit from the use of, and is adhering to, TTFT treatment, those claims may then be submitted with the KX modifier but only for dates of service following the date of the clinical re-evaluation.

Documentation of adherence to TTFT shall be accomplished through direct download or visual inspection of usage data with documentation provided in a written report format to be reviewed by the treating practitioner and included in the beneficiary's medical record. This information does not have to be submitted with the claim but must be available upon request.

If TTFT is interrupted for any reason, it is expected that the treating practitioner will document the reason for the interruption in therapy. This information does not have to be submitted with the claim but must be available upon request.

Documentation Requirements – General

There are numerous CMS manual requirements, reasonable and necessary requirements, benefit category, and other statutory and regulatory requirements that must be met in order for payment to be justified. In the event of a claim review, a DMEPOS supplier must provide sufficient information to demonstrate that the applicable criteria have been met thus justifying payment. Refer to the LCD, NCD or other CMS Manuals for more information on what documents may be required.

See Article A55426 Standard Documentation Requirements for All Claims Submitted to DME MACs.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
A4555	Electrode/transducer for use with electrical stimulation device used for cancer treatment, replacement only [Status Indicator 'I' (Invalid Code)]
E0766	Electrical stimulation device used for cancer treatment, includes all accessories, any type

Modifier	Description
KF	Item designated by FDA as Class III device
KX	Requirements specified in the medical policy have been met

Definitions

Karnofsky Performance Scale:

- 100 - Normal; 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
- 70 - Cares for self; unable to carry on normal activity or to do active work
- 60 - Requires occasional assistance but is able to care for most needs
- 50 - Requires considerable assistance and frequent medical care
- 40 - Disabled; requires special care and assistance
- 30 - Severely disabled; hospitalization is indicated although death not imminent

- 20 - Very sick; hospitalization necessary; active supportive treatment is necessary
- 10 - Moribund, fatal processes progressing rapidly
- 0 - Dead

References

CMS Local Coverage Determinations (LCDs) and Articles

LCD	Article	Contractor	DME MAC
L34823 Tumor Treatment Field Therapy (TTFT)	A52711 Tumor Treatment Field Therapy (TTFT) - Policy Article	CGS	AL, AR, CO, FL, GA, IL, IN, KY, LA, MI, MN, MS, NC, NM, OH, OK, PR, SC, TN, TX, VA, VI, WI, WV
	A55426 Standard Documentation Requirements for All Claims Submitted to DME MACs	Noridian	AK, AS, AZ, CA, CT, DC, DE, GU, HI, IA, ID, KS, MA, MD, ME, MO, MP, MT, ND, NE, NH, NJ, NV, NY, OR, PA, RI, SD, UT, VT, WA, WY

UnitedHealthcare Commercial Policy

[Electric Tumor Treatment Field Therapy](#)

Guideline History/Revision Information

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

Date	Summary of Changes
04/01/2021	<p>Template Update</p> <ul style="list-style-type: none"> ● Reformatted policy; transferred content to new template
08/12/2020	<p>Policy Summary</p> <p><i>Policy Specific Documentation Requirements</i></p> <ul style="list-style-type: none"> ● Removed language indicating: <ul style="list-style-type: none"> ○ In order to justify payment for DMEPOS items, suppliers must meet the following requirements: <ul style="list-style-type: none"> ▪ Prescription (orders) ▪ Medical Record Information (including continued need/use if applicable) ▪ Correct Coding ▪ Proof of Delivery ○ Items billed before a signed and dated order has been received by the supplier must be submitted with an EY modifier added to each affected HCPCS code <p><i>Documentation Requirements – General (new to policy)</i></p> <ul style="list-style-type: none"> ● Added language to indicate: <ul style="list-style-type: none"> ○ There are numerous CMS manual requirements, reasonable and necessary requirements, benefit category, and other statutory and regulatory requirements that must be met in order for payment to be justified ○ In the event of a claim review, a DMEPOS supplier must provide sufficient information to demonstrate that the applicable criteria have been met thus justifying payment ○ Refer to the Local Coverage Determination (LCD), National Coverage Determination (NCD) or other CMS Manuals for more information on what documents may be required ○ See the Local Coverage Article (LCA) titled <i>Standard Documentation Requirements for All Claims Submitted to DME MACs (A55426)</i> <p>Applicable Codes</p> <ul style="list-style-type: none"> ● Removed Modifier codes EY and GZ

Date	Summary of Changes
	Supporting Information <ul style="list-style-type: none"> Archived previous policy version MPG330.05

Purpose

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers' submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as NCDs, LCDs, LCAs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the [References](#) section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

Terms and Conditions

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

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*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the [Administrative Guide](#).