

Local Coverage Determination (LCD): Tumor Treatment Field Therapy (TTFT) (L34823)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
CGS Administrators, LLC	DME MAC	17013 - DME MAC	J-B	Illinois Indiana Kentucky Michigan Minnesota Ohio Wisconsin
CGS Administrators, LLC	DME MAC	18003 - DME MAC	J-C	Alabama Arkansas Colorado Florida Georgia Louisiana Mississippi New Mexico North Carolina Oklahoma Puerto Rico South Carolina Tennessee Texas Virgin Islands Virginia West Virginia
Noridian Healthcare Solutions, LLC	DME MAC	16013 - DME MAC	J-A	Connecticut Delaware District of Columbia Maine Maryland Massachusetts New Hampshire New Jersey New York - Entire State Pennsylvania Rhode Island Vermont

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Noridian Healthcare Solutions, LLC	DME MAC	19003 - DME MAC	J-D	Alaska American Samoa Arizona California - Entire State Guam Hawaii Idaho Iowa Kansas Missouri - Entire State Montana Nebraska Nevada North Dakota Northern Mariana Islands Oregon South Dakota Utah Washington Wyoming

LCD Information

Document Information

LCD ID

L34823

Original Effective Date

For services performed on or after 10/01/2015

LCD Title

Tumor Treatment Field Therapy (TTFT)

Revision Effective Date

For services performed on or after 01/01/2020

Proposed LCD in Comment Period

N/A

Revision Ending Date

N/A

Source Proposed LCD

DL34823

Retirement Date

N/A

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Notice Period Start Date

07/18/2019

Notice Period End Date

08/31/2019

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CMS National Coverage Policy

N/A

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

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.

The purpose of a Local Coverage Determination (LCD) is to provide information regarding “reasonable and necessary” criteria based on Social Security Act § 1862(a)(1)(A) provisions.

In addition to the “reasonable and necessary” criteria contained in this LCD there are other payment rules, which are discussed in the following documents, that must also be met prior to Medicare reimbursement:

- The LCD-related Standard Documentation Requirements Article, located at the bottom of this policy under the Related Local Coverage Documents section.

- The LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- Refer to the Supplier Manual for additional information on documentation requirements.
- Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

For the items addressed in this LCD, 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.

INITIAL COVERAGE FOR NEWLY DIAGNOSED GLIOBLASTOMA MULTIFORME:

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:

1. The beneficiary has histologically confirmed (World Health Organization (WHO) grade IV astrocytoma), newly diagnosed, supratentorial GBM; and,
2. The beneficiary has received initial treatment with maximal debulking surgery (when feasible), followed by chemotherapy and radiotherapy; and,
3. Tumor treatment field therapy is initiated within 7 weeks from the last dose of concomitant chemotherapy or radiotherapy, whichever is later; and,
4. The beneficiary has no evidence of progression by Response Assessment in Neuro-Oncology (RANO) criteria; and,
5. The beneficiary has a Karnofsky Performance Score (KPS) of at least 70; and,
6. 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. See Policy Specific Documentation Requirements in the LCD-related Policy Article, located in the Related Local Coverage Documents section of this LCD, for information about KX modifier use.

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.

BENEFICIARIES ENTERING MEDICARE

For beneficiaries who are undergoing treatment with TTFT for newly diagnosed, supratentorial GBM prior to enrollment in Fee-For-Service (FFS) Medicare and are seeking Medicare coverage of TTFT, coverage will be provided if all of the following coverage requirements are met:

- a. The beneficiary has been receiving TTFT following initial maximal debulking surgery (if feasible) followed by chemotherapy/radiotherapy for histologically confirmed newly diagnosed GBM; and,
- b. Clinical Evaluation – Following enrollment in FFS Medicare, the beneficiary must have an in-person evaluation by their treating practitioner who documents in the beneficiary's medical record that:
 1. The beneficiary is adherent with the use of TTFT for an average of 18 hours per day; and,
 2. The beneficiary is deriving benefit from the therapy.

If all of the above are not met, the claim will be denied as not reasonable and necessary.

GENERAL

A Standard Written Order (SWO) must be communicated to the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving a completed SWO, the claim shall be denied as not reasonable and necessary.

For Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) base items that require a Written Order Prior to Delivery (WOPD), the supplier must have received a signed SWO before the DMEPOS item is delivered to a beneficiary. If a supplier delivers a DMEPOS item without first receiving a WOPD, the claim shall be denied as not reasonable and necessary. Refer to the LCD-related Policy Article, located at the bottom of this policy under the

Related Local Coverage Documents section.

For DMEPOS base items that require a WOPD, and also require separately billed associated options, accessories, and/or supplies, the supplier must have received a WOPD which lists the base item and which may list all the associated options, accessories, and/or supplies that are separately billed prior to the delivery of the items. In this scenario, if the supplier separately bills for associated options, accessories, and/or supplies without first receiving a completed and signed WOPD of the base item prior to delivery, the claim(s) shall be denied as not reasonable and necessary.

An item/service is correctly coded when it meets all the coding guidelines listed in CMS HCPCS guidelines, LCDs, LCD-related Policy Articles, or DME MAC articles. Claims that do not meet coding guidelines shall be denied as not reasonable and necessary/incorrectly coded.

Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD documentation in their files. Proof of delivery documentation must be made available to the Medicare contractor upon request. All services that do not have appropriate proof of delivery from the supplier shall be denied as not reasonable and necessary.

Summary of Evidence

Support for TTFT in the treatment of newly diagnosed GBM stems from a study by Stupp et al. (2017), also referred to as the EF-14 study. The EF-14 study was a randomized, open-label trial of 695 patients with histologically-confirmed glioblastoma multiforme (World Health Organization (WHO) grade IV astrocytoma) whose tumor was resected or biopsied and had completed concomitant radiochemotherapy and TTFT. Of the 695 randomized patients, 637 (92%) completed the trial. Median progression-free survival from randomization was 6.7 months in the TTFT-temozolomide group vs 4.0 months in the temozolomide-alone group (HR, 0.63; 95% CI, 0.52-0.76; $P < .001$). Median overall survival was 20.9 months in the TTFT-temozolomide group vs 16.0 months in the temozolomide-alone group (HR, 0.63; 95% CI, 0.53-0.76; $P < .001$). Systemic adverse events were similar between the two study arms. Mild to moderate skin toxicity underneath the transducer arrays occurred in 52% of patients who received TTFT-temozolomide vs no patients who received temozolomide alone.

The *National Comprehensive Cancer Network* assigns TTFT a Category 1 recommendation as a treatment option for newly diagnosed GBM, following initial maximal debulking surgery (when feasible), chemotherapy, and radiation therapy.

Analysis of Evidence (Rationale for Determination)

Background

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.

Alternating electric fields are produced by a pulse generator and transmitted by ceramic transducers placed on a

patient's head. Tumor Treatment Field Therapy (TTFT) uses alternating electric fields to target cancer cells. 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.

NEWLY DIAGNOSED GBM

In October 2015 the FDA expanded the marketing indications for TTFT to include newly diagnosed GBM (see <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P100034S013>). In 2018 the DME MACs received a request to cover TTFT for newly diagnosed GBM.

Contractor Advisory Committee (CAC)

Following an independent review of the literature, the DME MACs assembled a 13-member specialty-focused CAC, comprised of a national panel of neuro-oncologists, neurosurgeons and experts in the field of oncologic treatment. The CAC meeting was held on March 6, 2019 in Baltimore, Maryland. Five (5) Key Questions were discussed by the CAC members, and confidence in each Key Question scored (Chair and Industry Representative were excluded from scoring). Confidence was rated on a scale of 1-5, with 1 indicative of low confidence and 5 indicating high confidence.

The following is a summary of the CAC Panel scoring for each Key Question and the related discussion.

- | 1. How confident are you that there is sufficient evidence to determine that TTFT for newly diagnosed GBM can provide net positive health outcomes in the Medicare-eligible population? | Scoring Member Average |
|--|-------------------------------|
|--|-------------------------------|

1 Low Confidence — 2 — 3 Intermediate — 4 — 5 High Confidence

3.82

The members noted that both Progression Free Survival (PFS) and Overall Survival (OS) were both increased in the EF-14 treatment arm, and migrated together, for both Medicare age eligible and non-eligible populations, in spite of the small group of the latter. Comments were made as to what constitutes adequate PFS and OS, and there was acknowledgement that additional months of improved quality of life in a disease such as GBM is a desirable outcome.

Several substantial concerns were raised in regard to net positive health outcomes. Two were related to study design, one to the philosophical approach to assessment of a new technology, and one to concerns related to conflicts of interest. In spite of the relative consensus on the goodness of metrics to reflect positive health outcomes, significant concerns were expressed at the study design, lack of sham control group and data gaps regarding volume of study subjects, subset analyses and the lack of corroborative additional clinical study. There was also discussion but not consensus as to whether or not the bar should be higher for net positive health outcomes for such a new technology. Additional concerns were related to the lack of clarity regarding clinical mechanism of action and concerns regarding delivery and dose effect, and geographical localization of the treatment field. Concerns related to potential conflict of interest in study funding and analyses were also discussed.

- | 2. How confident are you that the available evidence demonstrates adequate predictors of success in Medicare-eligible population? | Scoring Member |
|--|-----------------------|
|--|-----------------------|

Average

1 Low Confidence — 2 — 3 Intermediate — 4 — 5 High Confidence

3.45

When considering this question, there was repeated discussion of volume and data gaps. The most substantial concern revolved around the smallness of the Medicare age eligible subpopulation. There was consensus that predictors of response in the age eligible Medicare population were sparse.

- 3. How confident are you that TTFT is generally accepted by the medical community for newly diagnosed GBM?**

Scoring Member

Average

1 Low Confidence — 2 — 3 Intermediate — 4 — 5 High Confidence

2.91

This question generated the most concerns regarding how the standard of care was established, how the provider community was defined and segmented, and what conflicts may contribute to drive adoption. There was consensus that guidelines are just one factor in the determination as to whether TTF is generally accepted in the medical community.

In balance the group did think that regardless of how practitioners were notified of the availability of TTF for GBM, there was broad superficial penetration in the USA community, but that its acceptance as standard of care or generally accepted practice was not clear.

- 4. How confident are you that scientific evidence supports mitotic spindle disruption and cellular apoptosis as the mechanism of action of TTFT?**

Scoring Member

Average

1 Low Confidence — 2 — 3 Intermediate — 4 — 5 High Confidence

3.27

There was discussion here as to the lack of actual human data to demonstrate the mechanism of action, but consensus that there was a plethora of preclinical data did uniformly seem to demonstrate mitotic spindle disruption and apoptosis as a mechanism of action of tumor cell death.

- 5. How confident are you that there are no significant evidence gaps that may impact positive health outcomes in the Medicare-eligible population?**

Scoring Member

Average

1 Low Confidence — 2 — 3 Intermediate — 4 — 5 High Confidence

2.91

There was consensus in the group that there remained significant gaps in evidence that the CAC members would like to see explored, either through controlled trials or in a real world evidence study paradigms. There was consensus that more data is needed to identify the place of TTFT in therapy across a more broad range of patient population and within the treatment algorithm for GBM and to further explore its mechanism of action, prognostic features, and predictors of response.

There was discussion of the need to review the evolving evidence rapidly since the standard of care evolves so rapidly in this area. There was consensus that more data is needed to identify the place of TTFT in therapy across a more broad range of patient population and within the treatment algorithm for GBM and to further explore its mechanism of action, prognostic features, and predictors of response. Specific additional areas recommended for study included:

- **Dose density and power**
- **Demographic diversity of subjects**
- **Prognostic indicators**
- **Impact on caretakers**
- **More on quality of life**
- **Medical economic assessment**
- **The best sequencing of treatment including where in the algorithm is TTFT best placed**
- **Exploration of the human mechanism of action**

CONCLUSION

The use of TTFT for the treatment of newly diagnosed GBM appears to be gaining acceptance in the neuro-oncology community in the United States. The coverage requirements outlined above reflect the currently published literature with regard to criteria that best ensure optimal outcomes for Medicare beneficiaries with newly diagnosed GBM.

RECURRENT GBM

In April 2011 the Food and Drug Administration (FDA) approved the marketing of the NovoTTF-100A (later rebranded Optune®) for the treatment of recurrent GBM. The original LCD for TTFT was effective in August 2014, following an Open Meeting and solicitation of public comments. The DME MACs determined that, based on the strength and quality of the evidence available at that time, TTFT was not reasonable and necessary for the treatment of GBM.

In 2018 the DME MACs received a request to reconsider the decision on recurrent GBM. The requestor, Novocure, did not submit new evidence in support of revised coverage for recurrent disease. Consequently, pursuant to Chapter 13 of the *CMS Program Integrity Manual* (CMS Pub. 100-08), the DME MACs determined that the request was invalid.

Coding Information

CPT/HCPCS Codes

Group 1 Paragraph:

The appearance of a code in this section does not necessarily indicate coverage.

HCPCS MODIFIERS:

EY - No physician or other licensed health care provider order for this item or service

GA - Waiver of liability statement issued as required by payer policy, individual case

GZ - Item or service expected to be denied as not reasonable and necessary

KF - Item designated by FDA as Class III device

KX - Requirements specified in the medical policy have been met

HCPCS CODES:

Group 1 Codes:

CODE	DESCRIPTION
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

General Information

Associated Information

DOCUMENTATION REQUIREMENTS

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider." It is expected that the beneficiary's medical records will reflect the need for the care provided. The beneficiary's medical records include the treating practitioner's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available upon request.

GENERAL DOCUMENTATION REQUIREMENTS

In order to justify payment for DMEPOS items, suppliers must meet the following requirements:

- SWO
- Medical Record Information (including continued need/use if applicable)
- Correct Coding
- Proof of Delivery

Refer to the LCD-related Standard Documentation Requirements article, located at the bottom of this policy under the Related Local Coverage Documents section for additional information regarding these requirements.

Refer to the Supplier Manual for additional information on documentation requirements.

Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

Items covered in this LCD have additional policy-specific requirements that must be met prior to Medicare reimbursement.

Refer to the LCD-related Policy article, located at the bottom of this policy under the Related Local Coverage Documents section for additional information.

Appendices

Utilization Guidelines

Refer to Coverage Indications, Limitations and/or Medical Necessity

Sources of Information

Food and Drug Administration. Summary of Safety and Effectiveness Data. PMA P100034/S013. Novocure TTF-100A. October 5, 2015.

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Martinez-Garcia M, Alvarez-Linera J, Carrato C, et al. SEOM clinical guidelines for diagnosis and treatment of glioblastoma (2017). *Clin Transl Oncol*. 2018;20(1):22-28.

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Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
01/01/2020	R8	<p>Revision Effective Date: 01/01/2020 COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Revised: "face-to-face" to "in-person", where applicable Revised: Order information as a result of Final Rule 1713 CODING INFORMATION: Removed: Field titled "Bill Type" Removed: Field titled "Revenue Codes" Removed: Field titled "ICD-10 Codes that Support Medical Necessity" Removed: Field titled "ICD-10 Codes that DO NOT Support Medical Necessity" Removed: Field titled "Additional ICD-10 Information" DOCUMENTATION REQUIREMENTS: Revised: "physician's" to "treating practitioner's" GENERAL DOCUMENTATION REQUIREMENTS: Revised: Prescriptions (orders) to SWO</p> <p><i>02/27/2020: Pursuant to the 21st Century Cures Act, these revisions do not require notice and comment because they are due to non-discretionary coverage updates reflective of CMS FR-1713.</i></p>	<ul style="list-style-type: none"> • Provider Education/Guidance • Other
09/01/2019	R7	<p>Revision Effective Date: 09/01/2019 COVERAGE INDICATIONS, LIMITATIONS, AND/OR MEDICAL NECESSITY: Added: Criteria for Initial Coverage for Newly Diagnosed Glioblastoma Multiforme Added: Criteria for Continued Coverage for Newly Diagnosed GBM Beyond the First Three Months of Therapy Added: Coverage statement for Recurrent GBM Added: Coverage statement for Other Uses Added: Beneficiaries Entering Medicare FFS requirements SUMMARY OF EVIDENCE: Added: Summary of evidence reviewed ANALYSIS OF EVIDENCE (RATIONALE FOR DETERMINATION): Added: Background, CAC and key question information, and Conclusion HCPCS CODES: Added: HCPCS Modifiers GA, GZ, KF, and KX SOURCES OF INFORMATION:</p>	<ul style="list-style-type: none"> • Reconsideration Request

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		<p>Added: References to sources of information BIBLIOGRAPHY: Added: Bibliography information RELATED LOCAL COVERAGE DOCUMENTS: Added: Response to Comments: Tumor Treatment Field Therapy (TTFT) – DL34823</p>	
01/01/2017	R6	<p>No changes have been made to this LCD.</p> <p><i>03/29/2018: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.</i></p>	<ul style="list-style-type: none"> • Other
01/01/2017	R5	<p>Revision Effective Date: 01/01/2017 COVERAGE INDICATIONS, INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Added: New reference language and directions to Standard Documentation Requirements Added: General Requirements DOCUMENTATION REQUIREMENTS: Added: General Documentation Requirements Added: New reference language and directions to Standard Documentation Requirements POLICY SPECIFIC DOCUMENTATION REQUIREMENTS: Added: Direction to Standard Documentation Requirements Removed: PIM reference from Appendices SOURCES OF INFORMATION AND BASIS FOR DECISION: Removed: Sources of Information RELATED LOCAL COVERAGE DOCUMENTS: Added: LCD-related Standard Documentation Requirements article</p>	<ul style="list-style-type: none"> • Provider Education/Guidance
07/01/2016	R4	<p>Revision Effective Date: 07/01/2016 Links for Sources of Information and Basis for Decision updated.</p>	<ul style="list-style-type: none"> • Typographical Error
07/01/2016	R3	<p>Revision Effective Date: 07/01/2016 Links for Sources of Information and Basis for Decision updated.</p>	<ul style="list-style-type: none"> • Typographical Error

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
07/01/2016	R2	Effective July 1, 2016 oversight for DME MAC LCDs is the responsibility of CGS Administrators, LLC 18003 and 17013 and Noridian Healthcare Solutions, LLC 19003 and 16013. No other changes have been made to the LCDs.	<ul style="list-style-type: none"> Change in Assigned States or Affiliated Contract Numbers
10/01/2015	R1	Draft promoted to final.	<ul style="list-style-type: none"> Other (Draft LCD promoted to final.)

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Article(s)

A56688 - Response to Comments: Tumor Treatment Field Therapy (TTFT) - DL34823

A55426 - Standard Documentation Requirements for All Claims Submitted to DME MACs

A52711 - Tumor Treatment Field Therapy (TTFT) - Policy Article

Related National Coverage Documents

N/A

Public Version(s)

Updated on 02/21/2020 with effective dates 01/01/2020 - N/A

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Updated on 04/21/2017 with effective dates 01/01/2017 - 08/31/2019

Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.

Keywords

N/A

END OF LOCAL COVERAGE DETERMINATION

Per the Code of Federal Regulations, 42 C.F.R § 426. 325, only those portions of the currently effective Local Coverage Determination (LCD) that are based on section 1862(a)(1)(A) of the Social Security Act, may be challenged through an acceptable complaint as described in 42 C.F.R § 426.400. Also, per 42 C.F.R § 426.325 items that are not reviewable, and therefore cannot be challenged, include the Policy Article. Please note the distinction of the documents when reviewing the materials.

Local Coverage Article: Tumor Treatment Field Therapy (TTFT) - Policy Article (A52711)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
CGS Administrators, LLC	DME MAC	17013 - DME MAC	J-B	Illinois Indiana Kentucky Michigan Minnesota Ohio Wisconsin
CGS Administrators, LLC	DME MAC	18003 - DME MAC	J-C	Alabama Arkansas Colorado Florida Georgia Louisiana Mississippi New Mexico North Carolina Oklahoma Puerto Rico South Carolina Tennessee Texas Virgin Islands Virginia West Virginia
Noridian Healthcare Solutions, LLC	DME MAC	16013 - DME MAC	J-A	Connecticut Delaware District of Columbia Maine Maryland Massachusetts New Hampshire New Jersey New York - Entire State Pennsylvania Rhode Island Vermont

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Noridian Healthcare Solutions, LLC	DME MAC	19003 - DME MAC	J-D	Alaska American Samoa Arizona California - Entire State Guam Hawaii Idaho Iowa Kansas Missouri - Entire State Montana Nebraska Nevada North Dakota Northern Mariana Islands Oregon South Dakota Utah Washington Wyoming

Article Information

General Information

Article ID

A52711

Original Effective Date

10/01/2015

Original ICD-9 Article ID

[A52667](#)

[A52678](#)

[A52680](#)

[A52676](#)

Revision Effective Date

01/01/2020

Revision Ending Date

N/A

Article Title

Tumor Treatment Field Therapy (TTFT) - Policy Article

Retirement Date

N/A

Article Type

Article

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Article Guidance

Article Text:

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

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.

Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. "reasonable and necessary"). Tumor treatment field therapy devices are covered under the Durable Medical Equipment benefit (Social Security Act §1861(s)(6)). In order for a beneficiary's equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

Code E0766 is in the frequent and substantial service payment category. Items included in this payment category are reimbursed a single monthly fee schedule amount for the device and all related supplies and accessories. Separate billing of supplies and/or accessories will be denied as unbundling.

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

REQUIREMENTS FOR SPECIFIC DMEPOS ITEMS PURSUANT TO FINAL RULE 1713 (84 Fed. Reg Vol 217)

Final Rule 1713 (84 Fed. Reg Vol 217) requires a face-to-face encounter and a Written Order Prior to Delivery (WOPD) for specified HCPCS codes. CMS and the DME MACs provides a list of the specified codes, which is periodically updated. The link will be located here once it is available.

Claims for the specified items subject to Final Rule 1713 (84 Fed. Reg Vol 217) that do not meet the face-to-face encounter and WOPD requirements specified in the LCD- related Standard Documentation Requirements Article (A55426) will be denied as not reasonable and necessary.

If a supplier delivers an item prior to receipt of a WOPD, it will be denied as not reasonable and necessary. If the WOPD is not obtained prior to delivery, payment will not be made for that item even if a WOPD is subsequently obtained by the supplier. If a similar item is subsequently provided by an unrelated supplier who has obtained a WOPD prior to delivery, it will be eligible for coverage.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

In addition to policy specific documentation requirements, there are general documentation requirements that are applicable to all DMEPOS policies. These general requirements are located in the DOCUMENTATION REQUIREMENTS section of the LCD.

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 in the "Coverage Indications, Limitations and/or Medical Necessity" section of the related LCD ("Initial Coverage") have 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 in the "Coverage Indications, Limitations and/or Medical Necessity" section of the related LCD 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.

EQUIPMENT RETAINED FROM A PRIOR PAYER

When a beneficiary receiving a DMEPOS item from another payer (including a Medicare Advantage plan) becomes eligible for the Medicare Fee-For-Service (FFS) program, the first Medicare claim for that item or service is considered a new initial Medicare claim. Medicare does not automatically continue coverage for any item obtained from another payer when a beneficiary transitions to Medicare coverage.

For Medicare to provide payment, the beneficiary must meet all Medicare coverage, coding, and documentation requirements for the DMEPOS items in effect on the DOS of the initial Medicare claim.

A Proof of Delivery (POD) is required for all items, even those in the beneficiary's possession provided by another insurer prior to Medicare eligibility.

PROOF OF DELIVERY REQUIREMENTS FOR RECENTLY ELIGIBLE MEDICARE FFS BENEFICIARIES

The supplier record must document:

- A statement, signed and dated by the beneficiary (or beneficiary's designee), that the supplier has examined the item, meets the POD requirements; and,
- A supplier attestation that the item meets Medicare requirements.

Refer to the LCD-related Standard Documentation Requirements article, located at the bottom of this Policy Article under the Related Local Coverage Documents section for additional information regarding GENERAL

DOCUMENTATION REQUIREMENTS and the POLICY SPECIFIC DOCUMENTATION REQUIREMENTS.

MODIFIERS

GA, GZ, KF and KX MODIFIERS:

In all of the situations above describing use of the KX modifier, if all of the coverage criteria have not been met, the GA or GZ modifier must be added to a claim line for code E0766. When there is an expectation of a reasonable and necessary denial, suppliers must enter the GA modifier on the claim line if they have obtained a properly executed Advance Beneficiary Notice (ABN) or the GZ modifier if they have not obtained a valid ABN.

Claim lines billed without a GA, GZ or KX modifier will be rejected as missing information.

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. Claim lines billed without a KF modifier will be rejected as missing information.

MISCELLANEOUS

The supplier must enter the diagnosis code for code E0766 on each claim submitted.

Refer to the Supplier Manual for additional information on documentation requirements.

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.

Code E0766 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.

Suppliers should contact the Pricing, Data Analysis and Coding (PDAC) Contractor for guidance on the correct coding of these items.

Coding Information

CPT/HCPCS Codes

N/A

ICD-10 Codes that Support Medical Necessity
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N/A

ICD-10 Codes that DO NOT Support Medical Necessity

N/A

Additional ICD-10 Information

N/A

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

N/A

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

N/A

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
01/01/2020	R6	Revision Effective Date: 01/01/2020 REQUIREMENTS FOR SPECIFIC DMEPOS ITEMS PURSUANT TO FINAL RULE 1713 (84 Fed. Reg Vol 217): Added: Section and related information based on Final Rule 1713 MISCELLANEOUS: Removed: EY modifier language which is now incorporated in the SDR ICD-10 CODES THAT SUPPORT MEDICAL NECESSITY: Revised: Section header "ICD-10 Codes that are Covered" updated to "ICD-10 Codes that Support Medical Necessity" ICD-10 CODES THAT DO NOT SUPPORT MEDICAL NECESSITY:

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
		Revised: Section header "ICD-10 Codes that are Not Covered" updated to "ICD-10 Codes that DO NOT Support Medical Necessity" <i>02/27/2020: At this time 21st Century Cures Act applies to new and revised LCDs which require comment and notice. This revision is to an article that is not a local coverage determination.</i>
09/01/2019	R5	Revision Effective Date: 09/01/2019 POLICY SPECIFIC DOCUMENTATION REQUIREMENTS: Added: Documentation requirements for Initial Coverage (First Three Months) Added: Documentation requirements for Continued Coverage Beyond the First Three Months of Therapy Added: Documentation required for Equipment Retained From a Prior Payer Added: Proof of Delivery Requirements for Recently Eligible Medicare FFS Beneficiaries Added: GA, GZ, KF and KX modifier usage information Added: Miscellaneous information <i>07/18/2019: At this time 21st Century Cures Act applies to new and revised LCDs which require comment and notice. This revision is to an article that is not a local coverage determination.</i>
01/01/2017	R4	Revision Effective Date: 01/01/2017 POLICY SPECIFIC DOCUMENTATION REQUIREMENTS: Added: New reference language and directions to Standard Documentation Requirements RELATED LOCAL COVERAGE DOCUMENTS: Added: LCD-related Standard Documentation Requirements Language Article
07/01/2016	R3	Effective July 1, 2016 oversight for DME MAC Articles is the responsibility of CGS Administrators, LLC 18003 and 17013 and Noridian Healthcare Solutions, LLC 19003 and 16013. No other changes have been made to the Articles.
10/01/2015	R2	Revision Effective Date: 10/01/2014 Added: Associated Contractor Numbers
10/01/2015	R1	Draft policy article promoted to final.

Associated Documents

Related Local Coverage Document(s)

Article(s)

A55426 - Standard Documentation Requirements for All Claims Submitted to DME MACs

LCD(s)

L34823 - Tumor Treatment Field Therapy (TTFT)

Related National Coverage Document(s)

N/A

Statutory Requirements URL(s)

N/A

Rules and Regulations URL(s)

N/A

CMS Manual Explanations URL(s)

N/A

Other URL(s)

N/A

Public Version(s)

Updated on 02/21/2020 with effective dates 01/01/2020 - N/A

Updated on 07/12/2019 with effective dates 09/01/2019 - N/A

Updated on 04/21/2017 with effective dates 01/01/2017 - N/A

Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.

Keywords

N/A