# LCD - Transcutaneous Electrical Nerve Stimulators (TENS) (L33802)

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# Contractor Information

| CONTRACTOR NAME | CONTRACT TYPE | CONTRACT NUMBER | JURISDICTION | STATES |
|---|---|---|---|---|
| CGS Administrators, LLC | DME MAC | 17013 - DME MAC | J-B | Illinois<br>Indiana<br>Kentucky<br>Michigan<br>Minnesota<br>Ohio<br>Wisconsin |
| CGS Administrators, LLC | DME MAC | 18003 - DME MAC | J-C | Alabama<br>Arkansas<br>Colorado<br>Florida<br>Georgia<br>Louisiana<br>Mississippi<br>New Mexico<br>North Carolina<br>Oklahoma<br>Puerto Rico<br>South Carolina<br>Tennessee<br>Texas<br>Virgin Islands<br>Virginia<br>West Virginia |
| Noridian Healthcare Solutions, LLC | DME MAC | 16013 - DME MAC | J-A | Connecticut<br>Delaware<br>District of Columbia<br>Maine<br>Maryland<br>Massachusetts<br>New Hampshire<br>New Jersey<br>New York - Entire State<br>Pennsylvania<br>Rhode Island<br>Vermont |
| Noridian Healthcare Solutions, | DME MAC | 19003 - DME MAC | J-D | Alaska |

| CONTRACTOR NAME | CONTRACT TYPE | CONTRACT NUMBER | JURISDICTION | STATES |
|---|---|---|---|---|
| LLC | | | | American Samoa<br>Arizona<br>California - Entire State<br>Guam<br>Hawaii<br>Idaho<br>Iowa<br>Kansas<br>Missouri - Entire State<br>Montana<br>Nebraska<br>Nevada<br>North Dakota<br>Northern Mariana Islands<br>Oregon<br>South Dakota<br>Utah<br>Washington<br>Wyoming |

# LCD Information

## Document Information

**LCD ID**
L33802

**LCD Title**
Transcutaneous Electrical Nerve Stimulators (TENS)

**Proposed LCD in Comment Period**
N/A

**Source Proposed LCD**
N/A

**Original Effective Date**
For services performed on or after 10/01/2015

**Revision Effective Date**
For services performed on or after 11/20/2021

**AMA CPT / ADA CDT / AHA NUBC Copyright Statement**

**Revision Ending Date**
N/A

**Retirement Date**
N/A

**Notice Period Start Date**
N/A

**Notice Period End Date**
N/A



## CMS National Coverage Policy

CMS Manual System, Pub. 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Section 10.2, 160.7.1, 160.13, 160.27, 280.13

## 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.

The practitioner ordering the Transcutaneous Electrical Nerve Stimulators (TENS) unit and related supplies must be the treating practitioner for the disease or condition justifying the need for the TENS unit.

A TENS is covered for the treatment of beneficiaries with chronic, intractable pain or acute post-operative pain when one of the following coverage criteria, I or II, are met.

- Acute Post-operative Pain

TENS is covered for acute post-operative pain. Coverage is limited to 30 days (one month's rental) from the day of surgery. Payment will be made only as a rental.
A TENS unit will be denied as not reasonable and necessary for acute pain (less than three months duration) other than for post-operative pain.

- Chronic Pain Other than Low Back Pain
  TENS is covered for chronic, intractable pain other than chronic low back pain when all of the following criteria must be met:
  - The presumed etiology of the pain must be a type that is accepted as responding to TENS therapy. Examples of conditions for which TENS therapy is not considered to be reasonable and necessary are (not all-inclusive):
    - headache
    - visceral abdominal pain
    - pelvic pain
    - temporomandibular joint (TMJ) pain
  - The pain must have been present for at least three months.
  - Other appropriate treatment modalities must have been tried and failed.

  TENS therapy for chronic pain that does not meet these criteria will be denied as not reasonable and necessary.

TENS therapy for Chronic Low Back Pain (CLBP) will be denied as not reasonable and necessary.

General Requirements for chronic pain (II)

When used for the treatment of chronic, intractable pain described in section II, the TENS unit must be used by the beneficiary on a trial basis for a minimum of one month (30 days), but not to exceed two months. The trial period will be paid as a rental. The trial period must be monitored by the treating practitioner to determine the effectiveness of the TENS unit in modulating the pain. For coverage of a purchase, the treating practitioner must determine that the beneficiary is likely to derive significant therapeutic benefit from continuous use of the unit over a long period of time.

A 4-lead TENS unit may be used with either 2 leads or 4 leads, depending on the characteristics of the beneficiary's pain. If it is ordered for use with 4 leads, the medical record must document why 2 leads are insufficient to meet the beneficiary’s needs.

Supplies

Separate allowance will be made for replacement supplies when they are reasonable and necessary and are used with a covered TENS. Usual maximum utilization is:

- 2 TENS leads - a maximum of one unit of A4595 per month.
- 4 TENS leads - a maximum of two units of A4595 per month.

If the use of the TENS unit is less than daily, the frequency of billing for the TENS supply code should be reduced proportionally.

Replacement of lead wires (A4557) more often than every 12 months would rarely be reasonable and necessary.

A conductive garment (E0731) used with a TENS unit is rarely reasonable and necessary, but is covered only if all of

the following conditions are met:

- It has been prescribed by the treating practitioner for use in delivering covered TENS treatment.
- One of the medical indications outlined below is met:
    - The beneficiary cannot manage without the conductive garment because:
        - There is such a large area or so many sites to be stimulated, and
        - The stimulation would have to be delivered so frequently that it is not feasible to use conventional electrodes, adhesive tapes, and lead wires.
    - The beneficiary cannot manage without the conductive garment for the treatment of chronic intractable pain because the areas or sites to be stimulated are inaccessible with the use of conventional electrodes, adhesive tapes, and lead wires.
    - The beneficiary has a documented medical condition, such as skin problems, that preclude the application of conventional electrodes, adhesive tapes, and lead wires.
    - The beneficiary requires electrical stimulation beneath a cast to treat chronic intractable pain.

A conductive garment is not covered for use with a TENS device during the trial period unless:

- The beneficiary has a documented skin problem prior to the start of the trial period, and
- The TENS is reasonable and necessary for the beneficiary.

If the criteria above are not met for E0731, it will be denied as not reasonable and necessary.

Reimbursement for supplies is contingent upon use with a covered TENS unit. Claims for TENS supplies provided when there is no covered TENS unit 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

REFILL REQUIREMENTS

For DMEPOS items and supplies provided on a recurring basis, billing must be based on prospective, not retrospective use. For DMEPOS products that are supplied as refills to the original order, suppliers must contact the beneficiary prior to dispensing the refill and not automatically ship on a pre-determined basis, even if authorized by the beneficiary. This shall be done to ensure that the refilled item remains reasonable and necessary, existing supplies are approaching exhaustion, and to confirm any changes or modifications to the order. Contact with the beneficiary or designee regarding refills must take place no sooner than 14 calendar days prior to the delivery/shipping date. For delivery of refills, the supplier must deliver the DMEPOS product no sooner than 10 calendar days prior to the end of usage for the current product. This is regardless of which delivery method is utilized.

For all DMEPOS items that are provided on a recurring basis, suppliers are required to have contact with the beneficiary or caregiver/designee prior to dispensing a new supply of items. Suppliers must not deliver refills without a refill request from a beneficiary. Items delivered without a valid, documented refill request will be denied as not reasonable and necessary.

Suppliers must not dispense a quantity of supplies exceeding a beneficiary's expected utilization. Suppliers must stay attuned to changed or atypical utilization patterns on the part of their clients. Suppliers must verify with the treating practitioners that any changed or atypical utilization is warranted. Regardless of utilization, a supplier must not dispense more than a three (3) - month quantity at a time.

**Summary of Evidence**

N/A

**Analysis of Evidence (Rationale for Determination)**

N/A

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# 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

KX - Requirements specified in the medical policy have been met

**HCPCS CODES:**

**EQUIPMENT**

**Group 1 Codes:** (3 Codes)

| CODE | DESCRIPTION |
|---|---|
| E0720 | TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION (TENS) DEVICE, TWO LEAD, LOCALIZED STIMULATION |
| E0730 | TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION (TENS) DEVICE, FOUR OR MORE LEADS, FOR MULTIPLE NERVE STIMULATION |
| E0731 | FORM FITTING CONDUCTIVE GARMENT FOR DELIVERY OF TENS OR NMES (WITH CONDUCTIVE FIBERS SEPARATED FROM THE PATIENT'S SKIN BY LAYERS OF FABRIC) |

**Group 2 Paragraph:**

**SUPPLIES**

**Group 2 Codes:** (2 Codes)

| CODE | DESCRIPTION |
|---|---|
| A4557 | LEAD WIRES, (E.G., APNEA MONITOR), PER PAIR |
| A4595 | ELECTRICAL STIMULATOR SUPPLIES, 2 LEAD, PER MONTH, (E.G., TENS, NMES) |

# 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.

**Miscellaneous**

**Appendices**

**Utilization Guidelines**

Refer to Coverage Indications, Limitations, and/or Medical Necessity

**Sources of Information**

Reserved for future use.

**Bibliography**

N/A

# Revision History Information

| REVISION HISTORY DATE | REVISION HISTORY NUMBER | REVISION HISTORY EXPLANATION | REASONS FOR CHANGE |
|---|---|---|---|
| 11/20/2021 | R8 | **Revision Effective Date: 11/20/2021**<br>COVERAGE INDICATIONS, LIMITATIONS, AND/OR MEDICAL NECESSITY:<br>Removed: Criterion III Chronic Lower Back Pain (CLBP) due to coverage expired June 7, 2015 under NCD 160.27<br>Added: Not reasonable and necessary statement in accordance with NCD 160.27<br>CODING INFORMATION:<br>Removed: Modifier Q0 under HCPCS Modifiers section<br>APPENDICES:<br>Removed: CLBP clinical trial references<br><br>*10/7/2021: In accordance with NCD 160.27, coverage of TENS for CLBP is no longer available under Coverage with Evidence Development. Per the NCD, TENS is not reasonable and necessary for the treatment of CLBP under section 1862(a)(1)(A) of the Act. As a result, the DME MACs are removing this requirement as a non-discretionary change to the LCD, per the Program Integrity Manual, Chapter 13, §13.2.4.* | • Provider Education/Guidance<br>• Other |
| 01/01/2020 | R7 | **Revision Effective Date: 01/01/2020:**<br>COVERAGE INDICATIONS, LIMITATIONS, AND/OR MEDICAL NECESSITY:<br>Revised: "physician" to "practitioner"<br>Removed: Statement to refer to ICD-10 Codes that are Covered section in the LCD-related PA<br>Added: Statement to refer to ICD-10 code list in the LCD-related Policy Article<br>Revised: "physician" to "treating practitioner"<br>GENERAL:<br>Revised: Order information as a result of Final Rule 1713<br>REFILL REQUIREMENTS:<br>Revised: "ordering physicians" to "treating practitioners"<br>CODING INFORMATION:<br>Removed: Field titled "Bill Type"<br>Removed: Field titled "Revenue Codes"<br>Removed: Field titled "ICD-10 Codes that Support Medical Necessity"<br>Removed: Field titled "ICD-10 Codes that DO NOT Support Medical Necessity"<br>Removed: Field titled "Additional ICD-10 Information"<br>DOCUMENTATION REQUIREMENTS:<br>Revised: "physician's" to "treating practitioner's"<br>GENERAL DOCUMENTATION REQUIREMENTS:<br>Revised: "Prescriptions (orders)" to "SWO" | • Provider Education/Guidance<br>• Other |

| REVISION HISTORY DATE | REVISION HISTORY NUMBER | REVISION HISTORY EXPLANATION | REASONS FOR CHANGE |
|---|---|---|---|
| | | *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.* | |
| 01/01/2019 | R6 | **Revision Effective Date: 01/01/2019**<br>COVERAGE INDICATIONS, LIMITATIONS, AND/OR MEDICAL NECESSITY:<br>Removed: Statement to refer to diagnosis code section below<br>Added: Refer to Covered ICD-10 Codes in the LCD-related Policy Article<br>ICD-10 CODES THAT SUPPORT MEDICAL NECESSITY:<br>Moved: All diagnosis codes to the LCD-related Policy Article diagnosis code section per CMS instruction<br>ICD-10 CODES THAT DO NOT SUPPORT MEDICAL NECESSITY:<br>Moved: Statement about noncovered diagnosis codes moved to LCD-related Policy Article noncovered diagnosis code section per CMS instruction | • Other (ICD-10 code relocation per CMS instruction) |
| 10/01/2017 | R5 | **Revision Effective Date: 10/01/2017**<br>ICD-10 CODES THAT SUPPORT MEDICAL NECESSITY:<br>Added: New ICD-10 codes<br>Deleted: Non-valid ICD-10 (effective 10/01/2015)<br><br>11/30/2017: 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. | • Provider Education/Guidance<br>• Revisions Due To ICD-10-CM Code Changes |
| 01/01/2017 | R4 | **Revision Effective Date: 01/01/2017**<br>COVERAGE INDICATIONS, INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY:<br>Removed: Standard Documentation Language<br>Added: New reference language and directions to Standard Documentation Requirements<br>Added: General Requirements<br>Revised: Refill Requirements<br>DOCUMENTATION REQUIREMENTS:<br>Removed: Standard Documentation Language<br>Added: General Documentation Requirements | • Provider Education/Guidance |

| REVISION HISTORY DATE | REVISION HISTORY NUMBER | REVISION HISTORY EXPLANATION | REASONS FOR CHANGE |
|---|---|---|---|
| | | Added: New reference language and directions to Standard Documentation Requirements<br>POLICY SPECIFIC DOCUMENTATION REQUIREMENTS:<br>Removed: Standard Documentation Language<br>Added: Direction to Standard Documentation Requirements<br>Removed: Supplier Manual reference under Miscellaneous<br>Removed: PIM reference under Appendices<br>RELATED LOCAL COVERAGE DOCUMENTS:<br>Added: LCD-related Standard Documentation Requirements article | |
| 07/01/2016 | R3 | 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. | • Change in Assigned States or Affiliated Contract Numbers |
| 10/01/2015 | R2 | Revision Effective Date: 10/31/2014<br>COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY:<br>Revised: Standard Documentation Language to add covered prior to a beneficiary's Medicare eligibility<br>DOCUMENTATION REQUIREMENTS:<br>Revised: Standard Documentation Language for WOPD to make consistent with ACA requirements<br>Revised: Standard Documentation Language to add who can enter date of delivery date on the POD<br>Added: Instructions for Equipment Retained from a Prior Payer<br>Added: Repair/Replacement section | • Provider Education/Guidance |
| 10/01/2015 | R1 | **Revision Effective Date: 10/01/2015**<br>ICD-10 CODES THAT SUPPORT MEDICAL NECESSITY:<br>ICD-10 diagnosis codes updated based on ICD-10 Conversion/Coding Infrastructure Revisions/ICD-9 Updates to National Coverage Determinations (NCDs) Maintenance CR | • Revisions Due To ICD-10-CM Code Changes |

# Associated Documents

**Attachments**

TENS CMN CMS 848 (131 KB) (Uploaded on 03/10/2020)

**Related Local Coverage Documents**

**Articles**

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

A52520 - Transcutaneous Electrical Nerve Stimulators (TENS) - Policy Article

**Related National Coverage Documents**

N/A

**Public Versions**

| UPDATED ON | EFFECTIVE DATES | STATUS |
|---|---|---|
| 10/01/2021 | 11/20/2021 - N/A | Currently in Effect (This Version) |
| 02/21/2020 | 01/01/2020 - 11/19/2021 | Superseded |
| Some older versions have been archived. Please visit the MCD Archive Site to retrieve them. | | |

# Keywords

N/A