Local Coverage Determination (LCD) for Transcutaneous Electrical Nerve Stimulators (TENS) (L11495)

Section Navigation

Jump to Section...

Go

Contractor Information

Contractor Name	Contractor Number	Contractor Type
Noridian Administrative Services	19003	DME MAC

Back to Top

LCD Information

Document Information

LCD ID Number
L11495

LCD Title
Transcutaneous Electrical Nerve Stimulators (TENS)

Contractor's Determination Number
TENS

Primary Geographic Jurisdiction
Alaska
American Samoa
Arizona
California - Entire State
Northern Mariana Islands
Guam
Hawaii
Iowa
Idaho
Kansas
Missouri - Entire State
Montana
North Dakota
Nebraska
Nevada
Oregon
South Dakota
Utah
Washington
Wyoming

Oversight Region
Region X

DME Region LCD Covers
Jurisdiction D

Original Determination Effective Date
For services performed on or after 10/01/1993

Original Determination Ending Date

Revision Effective Date
For services performed on or after 06/08/2012

Revision Ending Date

CMS National Coverage Policy

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

Indications and Limitations of Coverage 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. For the items addressed in this local coverage determination, the criteria for "reasonable and necessary", based on Social Security Act §1862(a)(1)(A) provisions, are defined by

the following indications and limitations of coverage and/or medical necessity.

A transcutaneous electrical nerve stimulator (TENS) (E0720, E0730) requires a written order prior to delivery. Refer to the Documentation Requirements section of this LCD and to the Non-medical Necessity Coverage and Payment Rules section of the related Policy Article for information about these prescription requirements.

The physician ordering the TENS unit and related supplies must be the treating physician 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-III, are met.

I. Acute Post-operative Pain

TENS is covered for acute post-operative pain. Coverage is limited to 30 days 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.

II. 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.

III. Chronic Low Back Pain (CLBP)

TENS therapy for CLBP is only covered when all of the following criteria are met:

- The beneficiary has one of the following ICD-9 diagnoses:
  - 353.4 Lumbosacral root lesions, not elsewhere classified
  - 720.2 Sacroiliitis, not elsewhere classified
  - 721.3 Lumbosacral spondylosis without myelopathy
  - 721.42 Thoracic or lumbar spondylosis with myelopathy – lumbar region
  - 722.10 Lumbar intervertebral disc without myelopathy
  - 722.52 Lumbosacral intervertebral disc
  - 722.73 Intervertebral disc disorder myelopathy – lumbar region
  - 722.83 Post laminectomy syndrome – lumbar region
  - 722.93 Other and unspecified disc disorders, lumbar region
  - 724.02 Spinal stenosis, lumbar region without neurogenic claudication
  - 724.03 Spinal stenosis, lumbar region with neurogenic claudication
  - 724.2 Lumbago
  - 724.3 Sciatica
  - 724.4 Thoracic or lumbosacral neuritis or radiculitis, unspecified, radicular syndrome of lower extremities
  - 738.4 Acquired spondylolysthesis
  - 739.3 Non-allopathetic lesions NEC (not elsewhere classified) – lumbar region
  - 756.11 Spondylosysis, lumbosacral region
  - 756.12 Spondylolisthesis
  - 805.4 Fracture of vertebral column without mention of spinal cord injury, lumbar, closed
  - 806.4 Fracture of vertebral column with mention of spinal cord injury, lumbar, closed
  - 846.0 Sprains and strains of sacroiliac region – lumbosacral (joint) (ligament)
  - 846.1 Sprains and strains of sacroiliac ligament
  - 847.2 Sprains and strains of other and unspecified parts of back, lumbar
  - 953.2 Injury to nerve roots and spinal plexus, lumbar root
- The beneficiary is enrolled in an approved clinical study that meets all of the requirements set out in NCD §160.27 (CMS Internet Only Manual 100-3, Chapter 1). Refer to the APPENDICES section for additional information about approved clinical studies.

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

General Requirements for chronic pain (II) and CLBP (III)

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 physician to determine the effectiveness of the TENS unit in modulating the pain. For coverage of a purchase, the physician 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.

TENS used for CLBP as described in section III does not require a trial rental period or an assessment of effectiveness by the treating physician. Upon the beneficiary's enrollment into an approved study, the TENS is eligible for purchase.

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 physician 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.

Effective for claims with dates of service on or after June 8, 2012 supplies provided for use with a previously covered TENS unit used for CLBP (not as part of an approved study) are not eligible for reimbursement. These supply claims will 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. (CMS Program Integrity Manual, Internet-Only Manual, CMS Pub. 100-8, Chapter 5, Section 5.2.6).

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 ordering physicians that any changed or atypical utilization is warranted. Regardless of utilization, a supplier must not dispense more than a 3-month quantity at a time.

Back to Top

Coding Information

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.

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.

CPT/HCPCS Codes
The appearance of a code in this section does not necessarily indicate coverage.

HCPCS MODIFIERS:

EY - No physician or other 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

Q0 (zero) - Investigational clinical service provided in a clinical research study that is in an approved clinical research study

EQUIPMENT:

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)

SUPPLIES:

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

ICD-9 Codes that Support Medical Necessity
For TENS (E0720, E0730) used for CLBP when the approved clinical study (criterion III) requirements are met.

353.4	LUMBOSACRAL ROOT LESIONS NOT ELSEWHERE CLASSIFIED
720.2	SACROILIITIS NOT ELSEWHERE CLASSIFIED
721.3	LUMBOSACRAL SPONDYLOSIS WITHOUT MYELOPATHY
721.42	SPONDYLOSIS WITH MYELOPATHY LUMBAR REGION
722.10	DISPLACEMENT OF LUMBAR INTERVERTEBRAL DISC WITHOUT MYELOPATHY
722.52	DEGENERATION OF LUMBAR OR LUMBOSACRAL INTERVERTEBRAL DISC
722.73	INTERVERTEBRAL DISC DISORDER WITH MYELOPATHY LUMBAR REGION
722.83	POSTLAMINECTOMY SYNDROME OF LUMBAR REGION
722.93	OTHER AND UNSPECIFIED DISC DISORDER OF LUMBAR REGION
724.02	SPINAL STENOSIS, LUMBAR REGION, WITHOUT NEUROGENIC CLAUDICATION
724.03	SPINAL STENOSIS, LUMBAR REGION, WITH NEUROGENIC CLAUDICATION
724.2	LUMBAGO
724.3	SCIATICA
724.4	THORACIC OR LUMBOSACRAL NEURITIS OR RADICULITIS UNSPECIFIED
738.4	ACQUIRED SPONDYLOLISTHESIS
739.3	NONALLOPATHIC LESIONS OF LUMBAR REGION NOT ELSEWHERE CLASSIFIED
756.11	CONGENITAL SPONDYLOLYSIS LUMBOSACRAL REGION
756.12	SPONDYLOLISTHESIS CONGENITAL
805.4	CLOSED FRACTURE OF LUMBAR VERTEBRA WITHOUT SPINAL CORD INJURY
806.4	CLOSED FRACTURE OF LUMBAR SPINE WITH SPINAL CORD INJURY
846.0	LUMBOSACRAL (JOINT) (LIGAMENT) SPRAIN
846.1	SACROILIAC (LIGAMENT) SPRAIN
847.2	LUMBAR SPRAIN
953.2	INJURY TO LUMBAR NERVE ROOT

For other uses of TENS (acute post-operative pain (criterion I), chronic pain other than CLBP(criterion II)), there are no specified diagnosis codes

Diagnoses that Support Medical Necessity

ICD-9 Codes that DO NOT Support Medical Necessity
For TENS used for CLBP as part of an approved study, all codes not specified above

For all other TENS uses, not specified

ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation

Diagnoses that DO NOT Support Medical Necessity
Not specified.

Back to Top

General Information

Documentations 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 physician'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.

PRESCRIPTION (ORDER) REQUIREMENTS

GENERAL (PIM 5.2.1)

All items billed to Medicare require a prescription. An order for each item billed must be signed and dated by the treating physician, kept on file by the supplier, and made available upon request. Items dispensed and/or billed that do not meet these prescription requirements and those below must be submitted with an EY modifier added to each affected HCPCS code.

DISPENSING ORDERS (PIM 5.2.2)

Equipment and supplies may be delivered upon receipt of a dispensing order except for those items that require a written order prior to delivery. A dispensing order may be verbal or written. The supplier must keep a record of the dispensing order on file. It must contain:

- Description of the item
- Beneficiary's name
- Prescribing Physician's name
- Date of the order and the start date, if the start date is different from the date of the order
- Physician signature (if a written order) or supplier signature (if verbal order)

For the “Date of the order” described above, use the date the supplier is contacted by the physician (for verbal orders) or the date entered by the physician (for written dispensing orders).

Signature and date stamps are not allowed. Signatures must comply with the CMS signature requirements outlined in PIM 3.3.2.4.

The dispensing order must be available upon request.

For items that are provided based on a dispensing order, the supplier must obtain a detailed written order before submitting a claim.

DETAILED WRITTEN ORDERS (PIM 5.2.3)

A detailed written order (DWO) is required before billing. Someone other than the ordering physician may produce the DWO. However, the ordering physician must review the content and sign and date the document. It must contain:

- Beneficiary's name
- Physician's name
- Date of the order and the start date, if start date is different from the date of the order
- Detailed description of the item(s) (see below for specific requirements for selected items)
- Physician signature and signature date

For items provided on a periodic basis, including drugs, the written order must include:

- Item(s) to be dispensed
- Dosage or concentration, if applicable
- Route of Administration
- Frequency of use
- Duration of infusion, if applicable
- Quantity to be dispensed
- Number of refills

For the “Date of the order” described above, use the date the supplier is contacted by the physician (for verbal orders) or the date entered by the physician (for written dispensing orders).

Frequency of use information on orders must contain detailed instructions for use and specific amounts to be dispensed. Reimbursement shall be based on the specific utilization amount only. Orders that only state “PRN” or “as needed” utilization estimates for replacement frequency, use, or consumption are not acceptable. (PIM 5.9)

The detailed description in the written order may be either a narrative description or a brand name/model number.

Signature and date stamps are not allowed. Signatures must comply with the CMS signature requirements outlined in PIM 3.3.2.4.

The DWO must be available upon request.

A prescription is not considered as part of the medical record. Medical information intended to demonstrate compliance with coverage criteria may be included on the prescription but must be corroborated by information contained in the medical record.

WRITTEN ORDERS PRIOR TO DELIVERY (PIM 5.2.4)

A detailed written order prior to delivery (WOPD) is required for TENS. The supplier must have received a WOPD that has been both signed and dated by the treating physician and meets the requirements for a DWO before dispensing the item.

MEDICAL RECORD INFORMATION

GENERAL (PIM 5.7 - 5.9)

The Indications and Limitations of Coverage and/or Medical Necessity section of this LCD contains numerous reasonable and necessary (R&N) requirements. The Nonmedical Necessity Coverage and Payment Rules section of the related Policy Article contains numerous non-reasonable and necessary, benefit category and statutory requirements that must be met in order for payment to be justified. Suppliers are reminded that:

- Supplier-produced records, even if signed by the ordering physician, and attestation letters (e.g. letters of medical necessity) are deemed not to be part of a medical record for Medicare payment purposes.
- Templates and forms, including CMS Certificates of Medical Necessity, are subject to corroboration with information in the medical record.

Information contained directly in the contemporaneous medical record is the source required to justify payment except as noted elsewhere for prescriptions and CMNs. The medical record is not limited to physician's office records but may include records from hospitals, nursing facilities, home health agencies, other healthcare professionals, etc. (not all-inclusive). Records from suppliers or healthcare professionals with a financial interest in the claim outcome are not considered sufficient by themselves for the purpose of determining that an item is reasonable and necessary.

CONTINUED USE

Continued use describes the ongoing utilization of supplies or a rental item by a beneficiary.

Suppliers are responsible for monitoring utilization of DMEPOS rental items and supplies. No monitoring of purchased items or capped rental items that have converted to a purchase is required. Suppliers must discontinue billing Medicare when rental items or ongoing supply items are no longer being used by the beneficiary.

Beneficiary medical records or supplier records may be used to confirm that a DMEPOS item continues to be used by the beneficiary. Any of the following may serve as documentation that an item submitted for reimbursement continues to be used by the beneficiary:

1. Timely documentation in the beneficiary's medical record showing usage of the item, related option/accessories and supplies
2. Supplier records documenting the request for refill/replacement of supplies in compliance with the Refill Documentation Requirements (This is deemed to be sufficient to document continued use for the base item, as well)
3. Supplier records documenting beneficiary confirmation of continued use of a rental item

Timely documentation is defined as a record in the preceding 12 months unless otherwise specified elsewhere in this policy.

CONTINUED MEDICAL NEED

For all DMEPOS items, the initial justification for medical need is established at the time the item(s) is first ordered; therefore, beneficiary medical records demonstrating that the item is reasonable and necessary are created just prior to, or at the time of, the creation of the initial prescription. For purchased items, initial months of a rental item or for initial months of ongoing supplies or drugs, information justifying reimbursement will come from this initial time period. Entries in the beneficiary's medical record must have been created prior to, or at the time of, the initial DOS to establish whether the initial reimbursement was justified based upon the applicable coverage policy.

For ongoing supplies and rental DME items, in addition to information described above that justifies the initial provision of the item(s) and/or supplies, there must be information in the beneficiary's medical record to support that the item continues to be used by the beneficiary and remains reasonable and necessary. Information used to justify continued medical need must be timely for the DOS under review. Any of the following may serve as documentation justifying continued medical need:

1. A recent order by the treating physician for refills
2. A recent change in prescription
3. A properly completed CMN or DIF with an appropriate length of need specified
4. Timely documentation in the beneficiary's medical record showing usage of the item.

Timely documentation is defined as a record in the preceding 12 months unless otherwise specified elsewhere in the policy.

REFILL DOCUMENTATION (PIM 5.2.5-6)

A routine refill prescription is not needed. A new prescription is needed when:

- There is a change of supplier
- There is a change in the item(s), frequency of use, or amount prescribed
- There is a change in the length of need or a previously established length of need expires
- State law requires a prescription renewal

For items that the beneficiary obtains in-person at a retail store, the signed delivery slip or a copy of the itemized sales receipt is sufficient documentation of a request for refill.

For items that are delivered to the beneficiary, documentation of a request for refill must be either a written document received from the beneficiary or a contemporaneous written record of a phone conversation/contact between the supplier and beneficiary. The refill request must occur and be documented before shipment. A retrospective attestation statement by the supplier or beneficiary is not sufficient. The refill record must include:

- Beneficiary's name or authorized representative if different than the beneficiary
- A description of each item that is being requested
- Date of refill request
- Information documenting that the beneficiary's remaining supply is approaching exhaustion by the expected delivery date
- For consumable supplies, i.e., those that are used up (e.g., ostomy or urological supplies, surgical dressings, etc.) - the supplier should assess the quantity of each item that the beneficiary still has remaining, to document that the amount remaining will be nearly exhausted on or about the supply anniversary date.
- For non-consumable supplies, i.e., those more durable items that are not used up but may need periodic replacement (e.g., PAP and RAD supplies) - the supplier should assess whether the supplies remain functional, providing replacement (a refill) only when the supply item(s) is no longer able to function. Document the functional condition of the item(s) being refilled in sufficient detail to demonstrate the cause of the dysfunction that necessitates replacement (refill).

This information must be kept on file and be available upon request.

PROOF OF DELIVERY (PIM 4.26, 5.8)

Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD documentation in their files. For medical review purposes, POD serves to assist in determining correct coding and billing information for claims submitted for Medicare reimbursement. Regardless of the method of delivery, the contractor must be able to determine from delivery documentation that the supplier properly coded the item(s), that the item(s) delivered are the same item(s) submitted for Medicare reimbursement and that the item(s) are intended for, and received by, a specific Medicare beneficiary.

Suppliers, their employees, or anyone else having a financial interest in the delivery of the item are prohibited from signing and accepting an item on behalf of a beneficiary (i.e., acting as a designee on behalf of the beneficiary). The signature and date the beneficiary or designee accepted delivery must be legible.

For the purpose of the delivery methods noted below, designee is defined as any person who can sign and accept the delivery of DMEPOS on behalf of the beneficiary.

Proof of delivery documentation must be available to the Medicare contractor on request. All services that do not have appropriate proof of delivery from the supplier will be denied and overpayments will be requested. Suppliers who consistently fail to provide documentation to support their services may be referred to the OIG for imposition of Civil Monetary Penalties or other administrative sanctions.

Suppliers are required to maintain POD documentation in their files. There are three methods of delivery:

1. Delivery directly to the beneficiary or authorized representative
2. Delivery via shipping or delivery service
3. Delivery of items to a nursing facility on behalf of the beneficiary

Method 1–Direct Delivery to the Beneficiary by the Supplier

Suppliers may deliver directly to the beneficiary or the designee. In this case, POD to a beneficiary must be a signed and dated delivery slip. The POD record must include:

- Beneficiary's name
- Delivery address
- Sufficiently detailed description to identify the item(s) being delivered (e.g., brand name, serial number, narrative description)
- Quantity delivered
- Date delivered
- Beneficiary (or designee) signature and date of signature

The date of signature on the delivery slip must be the date that the DMEPOS item was received by the beneficiary or designee. In instances where the supplies are delivered directly by the supplier, the date the beneficiary received the DMEPOS item must be the date of service on the claim.

Method 2–Delivery via Shipping or Delivery Service Directly to a Beneficiary

If the supplier utilizes a shipping service or mail order, the POD documentation must be a complete record tracking the item(s) from the DMEPOS supplier to the beneficiary. An example of acceptable proof of delivery would include both the supplier's own detailed shipping invoice and the delivery service's tracking information. The supplier's record must be linked to the delivery service record by some clear method like the delivery service's package identification number or supplier's invoice number for the package sent to the beneficiary. The POD record must include:

- Beneficiary's name
- Delivery address
- Delivery service's package identification number, supplier invoice number or alternative method that links the supplier's delivery documents with the delivery service's records.
- Sufficiently detailed description to identify the item(s) being delivered (e.g., brand name, serial number, narrative description)
- Quantity delivered
- Date delivered
- Evidence of delivery

If a supplier utilizes a shipping service or mail order, suppliers must use the shipping date as the date of service on the claim.

Suppliers may also utilize a return postage-paid delivery invoice from the beneficiary or designee as a POD. This type of POD record must contain the information specified above.

Method 3–Delivery to Nursing Facility on Behalf of a Beneficiary

When a supplier delivers items directly to a nursing facility, the documentation described for Method 1 (see above) is required.

When a delivery service or mail order is used to deliver the item to a nursing facility, the documentation described for Method 2 (see above) is required.

Regardless the method of delivery, for those beneficiaries that are residents of a nursing facility, information from the nursing facility showing that the item(s) delivered for the beneficiary's use were actually provided to and used by the beneficiary must be available upon request.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

CERTIFICATE OF MEDICAL NECESSITY (PIM 5.3)

For TENS provided under criteria I and II in the Indications and Limitations of Coverage and/or Medical Necessity, a Certificate of Medical Necessity (CMN), which has been completed, signed, and dated by the treating physician, must be kept on file by the supplier and made available upon request. The CMN may act as a substitute for the detailed written order if it contains the same information as required in a detailed written order. The CMN for TENS is CMS Form 848 (DME form 06.03B). In addition to the information that the physician enters in Section B, the supplier can use the space in Section C for other details of the order or the physician can enter the other details directly.

A new CMN is not required just because the supplier changes assignment status on the submitted claim.

A CMN is not needed for a TENS rental.

A CMN is not needed for TENS provided for CLBP provided as part of an approved clinical study.

For all claims for TENS and related supplies there must be information in the medical record demonstrating that the coverage criteria are met.

For acute post-operative pain covered under criterion I, there must be information about:

- the date of surgery

- the nature of the surgery
- the location and severity of the pain

For chronic pain covered under criterion II, there must be information in the medical record describing:

- the location of the pain
- the severity of the pain
- the duration of time the beneficiary has had the pain
- the presumed etiology of the pain
- prior treatment and results of that treatment
- reevaluation of the beneficiary at the end of the trial period, must indicate
    - how often the beneficiary used the TENS unit
    - the typical duration of use each time
    - the results (effectiveness of therapy)

For CLBP covered under criterion III, there must be information in the medical record describing:

- participation in an approved study
- the qualifying ICD-9 diagnosis

For CLBP, each claim must include:

- The ICD-9 diagnosis describing the CLBP
- The “clinicaltrials.gov” identifier number must be included in the narrative field on each claim.

Each claim for code E0731 must be accompanied by the brand, name and model number of the conductive garment.

KX, GA, GZ AND Q0 (zero) MODIFIERS:

Suppliers must add a KX modifier to code E0731 only if all of the criteria in the INDICATIONS AND LIMITATIONS OF COVERAGE AND/OR MEDICAL NECESSITY section of this policy have been met.

Suppliers must add a KX modifier and a Q0 (zero) modifier to codes E0720 and E0730 used for CLBP only if all of the criteria described in section III of the INDICATIONS AND LIMITATIONS OF COVERAGE AND/OR MEDICAL NECESSITY section of this policy have been met.

For the situation where a KX modifier is required, if all of the criteria in the INDICATIONS AND LIMITATIONS OF COVERAGE AND/OR MEDICAL NECESSITY section have not been met, the GA or GZ modifier must be added to these codes. 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.

If the beneficiary is not enrolled in an approved clinical study for CLBP, the Q0 (zero) must not be used.

Claim lines billed for E0720, E0730 and E0731 without a GA, GZ or KX modifier as specified above will be rejected as missing information.

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

Appendices
PIM citations above denote references to CMS Program Integrity Manual, Internet Only Manual 100-8.

TENS used to treat CLBP is provided under limited coverage. Reimbursement is only available for beneficiaries who are enrolled in an approved clinical trial. CMS maintains a list of policies that require study participation as a condition of coverage on the CMS web site. For each policy the approved studies are listed and a link provided to the study on the clinicaltrials.gov web site. The clinicaltrials.gov identifier number required on each claim is listed on this site.

Utilization Guidelines
Refer to Indications and Limitations of Coverage and/or Medical Necessity.

Sources of Information and Basis for Decision
Reserved for future use.

Advisory Committee Meeting Notes

Start Date of Comment Period
04/16/1993

End Date of Comment Period
05/31/1993

Start Date of Notice Period
08/01/1993

Revision History Number
TENS007

Revision History Explanation
Revision Effective Date: 06/08/2012
INDICATIONS AND LIMITATIONS OF COVERAGE AND MEDICAL NECESSITY:
Revised: Reformatted coverage criteria to separate the different coverage conditions
Revised: “Chronic pain” to separate CLBP from other types of chronic pain
Added: Coverage for CLBP to add diagnosis and approved study requirements (CR 7836)
HCPCS CODES AND MODIFIERS:
Added: Q0 (zero) modifier
ICD-9 CODES THAT SUPPORT MEDICAL NECESSITY
Added: Diagnosis for CLBP coverage
DOCUMENTATION REQUIREMENTS:

Revised: CMN requirements to exclude CLBP
Added: Guidance for documenting coverage
(Note: The effective date above is not applicable to the documentation revisions described below. These revised and added requirements are existing Medicare requirements which are now included in the LCD for easy reference)
Revised: Prescription requirements
Added: Refill requirements, general medical record information requirements, continued use and continued need requirements, and proof of delivery requirements
APPENDICES:
Added: Reference for PIM citations
Added: Information about “Coverage with Evidence Development” and “Clinicaltrials.gov” study identification number

Revision Effective Date: 01/01/2011
INDICATIONS AND LIMITATIONS OF COVERAGE AND MEDICAL NECESSITY:
Added: Preamble
Revised: "medically necessary" replaced with "reasonable and necessary"
HCPCS CODES AND MODIFIERS:
Revised: GA modifier narrative
DOCUMENTATION REQUIREMENTS:
Revised: "medically necessary" replaced with "reasonable and necessary"

Revision Effective Date: 12/01/2009
INDICATIONS AND LIMITATIONS OF COVERAGE:
Revised: Additional supply quantities denial statement
HCPCS CODES AND MODIFIERS:
Added: GA and GZ modifiers
Revised: KX modifier
DOCUMENTATION REQUIREMENTS:
Removed: Instructions for additional quantities
Added: Instructions for the use of GA and GZ modifiers

3/1/2008 - In accordance with Section 911 of the Medicare Modernization Act, this policy was transitioned to DME MAC Noridian Administrative Services (19003) LCD L11495 from DME PSC Electronic Data Systems Corp. (77006) LCD L11495.

Revision Effective Date: 01/01/2007
HCPCS CODES AND MODIFIERS:
Revised: E0720, E0730
DOCUMENTATION REQUIREMENTS:
Removed DMERC references
Removed reference to HCFA Form; changed to read "CMS" Form.
Provided new DME Form number
Revised instructions for use of CMN
LCD ATTACHMENTS:
Attached newly revised CMN Form for TENS

03/01/2006 - In accordance with Section 911 of the Medicare Modernization Act of 2003, this policy was transitioned to DME PSC Electronic Data Systems Corp. (77006) from DMERC CIGNA Government Services (05655).

Revision Effective Date: 01/01/2006
LMRP converted to an LCD and Policy Article.
INDICATIONS AND LIMITATIONS OF COVERAGE:
Added Medical Necessity denial if criteria for E0731 are not met.
DOCUMENTATION REQUIREMENTS:
Added KX modifier to be used with E0731 if criteria are met.
Removed requirement to submit additional documentation with claim.

Revision Effective Date: 04/01/2003
HCPCS CODES AND MODIFIERS:
Revised: A4595 and E0730, effective 01/01/2003
Added EY modifier
INDICATIONS AND LIMITATIONS OF COVERAGE:
Added: Standard language concerning coverage of items without an order.
Added: Language regarding the medical necessity for use of a greater quantity of supplies and the need for the items being documentated in beneficiary’s medical records.
DOCUMENTATION REQUIREMENTS:
Added: Standard language concerning use of EY modifier for items without an order.
Added: Items billed in excess quantities and the requirement.

The revision dates listed below are the dates the revisions were published and not necessarily the effective dates for the revisions.

01/01/2002 - The revisions include changes in coverage and payment rules, coding guidelines, and documentation requirements, as well as elimination of availability for prior authorization for this item.

10/01/1996 – HCPCS code K0118 crosswalked to A4595. Incorporated Indications section into Coverage and Payment Rules section. Revised Coverage and Payment Rules section.

12/01/1993 – Corrected HAO to HA0 in Documentation section.

Reason for Change

CMS Requirement
Coverage Change (actual change in medical parameters)
ICD9 Addition/Deletion

Related Documents

Article(s)
A37074 - Transcutaneous Electrical Nerve Stimulators (TENS) - Policy Article - Effective January 2011

LCD Attachments

There are no attachments for this LCD

Back to Top

All Versions

Updated on 10/14/2012 with effective dates 06/08/2012 - N/A
Updated on 03/08/2012 with effective dates 01/01/2011 - 06/07/2012
Updated on 03/01/2011 with effective dates 01/01/2011 - N/A
Updated on 02/27/2011 with effective dates 01/01/2011 - N/A
Updated on 08/30/2009 with effective dates 12/01/2009 - 12/31/2010
Updated on 03/25/2008 with effective dates 01/01/2007 - 11/30/2009
Updated on 02/19/2008 with effective dates 01/01/2007 - N/A

Back to Top

Read the LCD Disclaimer

Close

Local Coverage Article for Transcutaneous Electrical Nerve Stimulators (TENS) - Policy Article - Effective January 2011 (A37074)

Section Navigation

Go

Jump to Section...

Contractor Information

Contractor Name	Contractor Number	Contractor Type
Noridian Administrative Services	19003	DME MAC

Back to Top

Article Information

General Information

Article ID Number
A37074

Article Type
Article

Key Article
Yes

Article Title
Transcutaneous Electrical Nerve Stimulators (TENS) - Policy Article - Effective January 2011

Primary Geographic Jurisdiction
Alaska
American Samoa
Arizona
California - Entire State
Northern Mariana Islands
Guam
Hawaii
Iowa
Idaho
Kansas
Missouri - Entire State
Montana
North Dakota
Nebraska
Nevada
Oregon
South Dakota
Utah
Washington
Wyoming

DME Region Article Covers
Jurisdiction D

Original Article Effective Date
01/01/2006

Article Revision Effective Date
01/01/2011

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").

Transcutaneous electrical nerve stimulation equipment is covered under the Durable Medical Equipment benefit. 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

For an item addressed in this policy to be covered by Medicare, a written signed and dated order must be received by the supplier prior to delivery of the item. If the

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

During the rental of a TENS unit, supplies for the unit are included in the rental allowance; there is no additional allowance for electrodes, lead wires, batteries, etc. If a TENS unit (E0720 or E0730) is purchased, the allowance includes lead wires and one month's supply of electrodes, conductive paste or gel (if needed), and batteries.

CODING GUIDELINES

A transcutaneous electrical nerve stimulator (TENS) (E0720, E0730) is a device which utilizes electrical current delivered through electrodes placed on the surface of the skin to decrease the patient's perception of pain by inhibiting the transmission of afferent pain nerve impulses and/or stimulating the release of endorphins. A TENS unit must be distinguished from other electrical stimulators (e.g., neuromuscular stimulators) which are used to directly stimulate muscles and/or motor nerves.

A TENS supply allowance (A4595) includes electrodes (any type), conductive paste or gel (if needed, depending on the type of electrode), tape or other adhesive (if needed, depending on the type of electrode), adhesive remover, skin preparation materials, batteries (9 volt or AA, single use or rechargeable), and a battery charger (if rechargeable batteries are used).

Codes A4556 (Electrodes, [e.g., apnea monitor], per pair), A4558 (Conductive paste or gel), and A4630 (Replacement batteries, medically necessary TENS owned by patient) are not valid for claim submission to the DMERC. A4595 should be used instead.

For code A4557, one unit of service is for lead wires going to two electrodes. If all the lead wires of a 4 lead TENS unit needed to be replaced, billing would be for two units of service.

There should be no billing and there will be no separate allowance for replacement electrodes (A4556), conductive paste or gel (A4558), replacement batteries (A4630), or a battery charger used with a TENS unit.

Other supplies, including but not limited to the following, will not be separately allowed: adapters (snap, banana, alligator, tab, button, clip), belt clips, adhesive remover, additional connecting cable for lead wires, carrying pouches, or covers.

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

Back to Top

Coding Information

Back to Top

Other Information

Revision History Explanation
Revision Effective Date: 01/01/2011
NONMEDICAL NECESSITY COVERAGE AND PAYMENT RULES:
Added: Preamble
Added: Benefit category statement

Revision Effective Date: 12/01/2009
CODING GUIDELINES:
Changed: SADMERC to PDAC

03/01/2008 - In accordance with Section 911 of the Medicare Modernization Act, this policy was transitioned to DME MAC Noridian Administrative Services (19003) Article A37074 from DME PSC Electronic Data Systems Corp. (77006) Article A37074.

03/01/2006 - In accordance with Section 911 of the Medicare Modernization Act of 2003, this article was transitioned to DME PSC Electronic Data Systems Corp. (77006) from DMERC CIGNA Government Services (05655).

Related Document(s)
LCD(s)
L11495 - Transcutaneous Electrical Nerve Stimulators (TENS)

Back to Top

All Versions

Updated on 02/27/2011 with effective dates 01/01/2011 - N/A
Updated on 08/30/2009 with effective dates 12/01/2009 - N/A
Updated on 03/27/2008 with effective dates 03/01/2006 - N/A

Back to Top

Read the Article Disclaimer