MED
medical equipment

What's needed for a new referral:

- Demographics
- Detailed Written Order Signed/Dated by physician
- Most recent Face-To-Face note discussing the item the patient is needing as well as the diagnosis

TENS unit

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.

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 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.

- 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. this needs to be documented
  - 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.
- 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 diagnosis codes listed. (Refer to the "**ICD-10 Codes that are Covered**" section in the LCD-related Policy Article for applicable diagnoses.)
  - 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 100-03, 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 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.

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.

Refer to the COVERAGE INDICATIONS, LIMITATIONS, AND/OR MEDICAL NECESSITY section of the LCD for additional information about coverage criteria and associated documentation.

REQUIREMENTS FOR SPECIFIC DMEPOS ITEMS PURSUANT TO 42 CFR 410.38(g)

42 CFR 410.38(g) requires a face-to-face evaluation and a specific written order prior to delivery for specified HCPCS codes. CMS provides a list of the specified codes, which is periodically updated, located here.

Claims for the specified items subject to 42 CFR 410.38(g) that do not meet the requirements specified in the LCD-related Standard Documentation Requirements Article will be denied as statutorily noncovered – failed to meet statutory requirements.

If the supplier delivers the item prior to receipt of a written order, it will be denied as statutorily 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.

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.

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 discussed below.

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 of the related LCD, 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 of the related LCD, 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)

> after 30 day trial

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

- Participation in an approved study
- The qualifying diagnosis

For CLBP, each claim must include:

- The diagnosis describing the CLBP
- The "clinicaltrials.gov" identifier number must be included in the narrative field on each claim. Refer to the Appendices section of the related LCD for additional information.

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

CERTIFICATE OF MEDICAL NECESSITY (CMN)

For TENS provided under criteria I, II, and III in the Coverage Indications, Limitations, and/or Medical Necessity of the related LCD, 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 a written confirmation of 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.

MODIFIERS

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

Suppliers must add a KX modifier to codes E0720, E0730, and E0731 only if all of the criteria in the COVERAGE INDICATIONS, LIMITATIONS, AND/OR MEDICAL NECESSITY section of the related LCD have been met.

For the situation where a KX modifier is required, if all of the criteria in the COVERAGE INDICATIONS, LIMITATIONS, AND/OR MEDICAL NECESSITY section of the related LCD 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.

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

MEDX

medical equipment

DIABETIC SHOE PROGRAM

Dr. Comfort

APEX

DREW. Fit Comfort Style

Ped-Lite

MED medical equipment

DETAILED PHYSICIANS ORDER
DURABLE MEDICAL EQUIPMENT

Patient: _____ Date of Order: _____ HT: ____ WT: _____

Address: _____ DOB: _____ Length of Need: 99

_____ Diagnosis Codes: _____

Equipment Needed:

____ E1038 Transport chair (weight <= 300 lbs.)
____ K0001 Standard Manual Wheelchair
____ K0003 Lightweight Manual Wheelchair
____ K0004 High Strength Lightweight Manual Wheelchair
____ K0006 HD Manual Wheelchair (weight > 250 lbs.)
____ K0007 Extra HD Manual Wheelchair (weight > 300 lbs.)

Additional Accessories for K0001 – K0007 wheelchairs
Non Standard Seat Width
____ E2201 (>=20"-<24") ____ E2202 (24"-27")
____ Seat Cushion – Please specify:
E2601, E2602, E2603*, E2604*, E2622*, E2623*
____ Back Cushion – Please specify:
E2611, E2612
____ Heel Loops/ Standard leg rests (E0951) ___Right ____ Left
____ Elevating Leg rests (K0195) ___Right ___ Left
____ Articulating Leg rests (K0053)
____ Anti-Tippers (E0971) ___ Right ___ Left
____ Brake extensions (E0961) ___ Right ___ Left
____ Height adjustable arms (E0973) ___ Right ___ Left
____ Arm Trough (E2209)* ___ Right ___ Left
____ Amputee support (E1020)* ___ Right ___ Left
____ Swing away Hardware (E1028) ___ Right ___ Left
____ 1 arm drive attachment (E0958) ___ Right ___ Left
____ Lap tray (E0950)
____ Oxygen tank holder (E2208)
Verify covered diagnosis

____ E0260 Semi-electric hospital bed w/ mattress
____ E0261 Semi-electric hospital bed w/o mattress
____ E0265 Full electric hospital bed (ABN required)
____ E0303 HD hospital bed extra wide (350-600 lbs)
____ E0143 Standard Walker (No wheels)
____ E0143 Wheeled walker
____ E0143 Wheeled walker with seat (Rollator)
____ E0156 Walker Seat for Rollator
____ E0100 Cane-Standard Aluminum
____ E0105 Quad Cane (sm or lg)

____ **If other please specify:**

_____
_____
_____
_____
_____
_____

Physicians
Name: _____

Address: _____

_____

Phone: _____

Fax: _____

Physicians
Signature: _____
(Original no stamps please)

Date: _____

NPI: _____

Showroom location for new patients and walk-ins:
1005 N Kingshighway Ste 12 Cape Girardeau ph. 573-803-2390 fax. 573-803-1247