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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 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 (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.

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 diagnosis codes listed in the ICD-10 Codes that Support Medical Necessity section below.
- 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 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.

GENERAL

A Detailed Written Order (DWO) (if applicable) must be received by the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving a completed DWO, 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 also obtain a DWO before submitting a claim for any associated options, accessories, and/or supplies that are separately billed. In this scenario, if the supplier bills for associated options, accessories, and/or supplies without first receiving a completed DWO, the claim shall be denied as not reasonable and necessary.

A WOPD (if applicable) must be received by the supplier before a DMEPOS item is delivered to a beneficiary. If a supplier delivers a DMEPOS item without first receiving a completed WOPD, the claim shall be statutorily denied. Refer to the LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.

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 ordering physicians 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