

References: L11495, A37074 (prior to 10/01/2015); L33802, A52520 (on/after 10/01/2015), NCD 10.2, 160.7.1, 160.13, 160.27, 280.13

AIITENS (E0720, E0730) and Garments (E0731)

- □ Face-to-Face Examination (F2F)
 - Date stamp indicating supplier's date of receipt of F2F on or before date of delivery
- □ Written Order Prior to Delivery (WOPD)
 - Date stamp indicating supplier's date of receipt of WOPD on or before date of delivery

All TENS Supplies

- Detailed Written Order (DWO)
- Refill Requirements

All TENS, Garments, and Supplies

- Beneficiary Authorization
- □ Proof of Delivery (POD)
 - Method 1 Direct Delivery to the Beneficiary by the Supplier
 The date the beneficiary/designee signs for the equipment or supplies is to be the date of service of the claim.
 - Method 2 Delivery via Shipping or Delivery Service
 The shipping date is to be the date of service of the claim.
- □ Continued Need
- □ Continued Use

Medical Records

TENS Unit (E0720, E0730)

- □ 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.
- TENS is covered for the treatment of beneficiaries with chronic, intractable pain, or acute post-operative pain when one of the following coverage criteria are met:
 - □ Acute Post-operative Pain
 - Limited to 30 days from the day of surgery
 - D Payment made only as a rental
 - Documentation must include:

- Date of the surgery
- □ Nature of the surgery
- □ Location and severity of the pain; or
- Chronic Pain Other than Low Back Pain
 - Presumed etiology of the pain must be a type that is accepted as responding to TENS therapy; **and**
 - Pain must have been present for at least three (3) months; and
 - □ Other appropriate treatment modalities must have been tried and failed.
 - □ Information in the medical record must describe:
 - $\hfill\square$ Location of the pain
 - □ Severity of the pain
 - Duration of time the beneficiary has had the pain (pain must be present for at least 3 months)
 - □ Presumed etiology of the pain
 - D Prior treatment and results of that treatment
 - □ Reevaluation of the beneficiary at the end of the trial period indicating:
 - □ How often the beneficiary used the TENS unit
 - □ Typical duration of use each time
 - □ Results (effectiveness of therapy); or
- □ Chronic Low Back Pain (CLBP)
 - Beneficiary has one of the diagnoses listed in the Diagnosis Codes that Support Medical Necessity section of the LCD; and
 - Beneficiary is enrolled in an approved clinical study.
- General requirements for chronic pain
 - □ Must be used on a trial basis for a minimum 30 days, but not to exceed two (2) months.
 - Trial period will be paid as a rental; and
 - □ Trial period must be monitored by the physician to determine the effectiveness of the TENS unit in modulating the pain.
 - □ For coverage as a purchase, the physician must determine that the beneficiary is likely to derive significant therapeutic benefit from continuous use over a long period of time.
 - □ If ordered for use with 4 leads, the medical record must document why 2 leads are insufficient to meet the beneficiary's needs.
- □ General requirement for CLBP
 - □ If ordered for use with 4 leads, the medical record must document why 2 leads are insufficient to meet the beneficiary's needs.

Conductive Garment (E0731)

Conductive garment is only covered if all of the following conditions are met:

- Has been prescribed by the treating physician for use in delivering covered TENS treatment; and
- Beneficiary meets one of the covered medical indications:
 - Beneficiary cannot manage without the conductive garment because:
 - $\hfill\square$ There is such a large area or so many sites to be stimulated; and
 - □ Stimulation would have to be delivered so frequently that it is not feasible to use conventional electrodes, adhesive tape, and lead wires; **or**
 - 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; or
- Beneficiary has a documented medical condition, such as skin problems, that precludes the application of conventional electrodes, adhesive tapes and lead wires; or
- Beneficiary requires electrical stimulation beneath a cast to treat chronic intractable pain.
- □ Conductive Garment is only covered during the trial rental period if:
 - Beneficiary has a documented skin problem prior to the start of the trial period; and
 - □ TENS is reasonable and necessary for the beneficiary.

Certificate of Medical Necessity (CMN – CMS Form 848)

- 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
- □ CMN is not needed for a TENS rental

Billing Reminders

- Each claim for E0731 must include the brand, name and model number of the conductive garment.
- The KX modifier must be added to the code if all the coverage criteria noted above have been met.
- When there is an expectation of a medical necessity denial, the GA modifier must be added to the code if a valid Advance Beneficiary Notice (ABN) has been obtained or a GZ modifier if a valid ABN has not been obtained.
- Q0 (zero) modifier must be added to E0720 and E0730 used for CLBP in a clinical trial only if all the criteria have been met.
- ICD code(s) that justifies the need for the TENS unit when used in a clinical trial to treat CLBP must be included on the claim.
- "Clinicaltrials.gov" identifier number is required on each claim in which the beneficiary is enrolled in an approved clinical trial for the treatment of CLBP.

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Print Form

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