The supplier must be able to provide all of these items on request:

- Standard Written Order (SWO)
- Refill Requirements
- Beneficiary Authorization
- Proof of Delivery (POD)
- Continued Need
- Continued Use
- Medical records from treating practitioner as noted below

**Medical Records should contain:**

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
    - 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:

- 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
- 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 of 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 beneficiaries needs.

General requirements for CLBP

- If ordered for use with 4 leads, the medical record must document why 2 leads are insufficient to meet the beneficiaries needs.

Conductive Garment (E0731)

- Conductive garment is only covered if all of the following conditions are met:
  - Had 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 conduct garment because:
      - 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 conduct 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 conduction, such as skin problems, that precludes the application of conventional electrodes, adhesive tapes and lead wires; or

Beneficiary request electrical stimulation beneath a cast to treat chronic intractable pain;

Conductive garment is only covered during the trial rental period if:

- Beneficiary has 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