



June 7, 2012

Louis Jacques, MD
Director, Coverage and Analysis Group
Office of Clinical Standards and Quality
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

Dear Dr. Jacques,

The Agency for Healthcare Research and Quality (AHRQ) understands that the Centers for Medicare and Medicaid Services (CMS) will cover the use of transcutaneous electrical nerve stimulation (TENS) for chronic low back pain (CLBP) under section 1862(a)(1)(E) of the Social Security Act in order to support additional research on the use of TENS for CLBP. Coverage under this section of the Act expires three years after the publication of this decision on the CMS website, and is only for beneficiaries enrolled in an approved prospective clinical study that meets the criteria listed below:

- I. For the purposes of this decision, CLBP is defined as:
 1. an episode of low back pain that has persisted for three months or longer; and
 2. is not a manifestation of a clearly defined and generally recognizable primary disease entity. For example, there are cancers that, through metastatic spread to the spine or pelvis, may elicit pain in the lower back as a symptom; and certain systemic diseases such as rheumatoid arthritis and multiple sclerosis manifest many debilitating symptoms of which low back pain is not the primary focus.

- II. The study must address one or more aspects of the following questions in a randomized, controlled design using validated and reliable instruments. This can include randomized crossover designs when the impact of prior TENS use is appropriately accounted for in the study protocol.
 1. Does the use of TENS provide clinically meaningful reduction in pain in Medicare beneficiaries with CLBP?
 2. Does the use of TENS provide a clinically meaningful improvement of function in Medicare beneficiaries with CLBP?
 3. Does the use of TENS impact the utilization of other medical treatments or services used in the medical management of CLBP?

These studies must be designed so that the patients in the control and comparison groups receive the same concurrent treatments and either sham (placebo) TENS or active TENS intervention.

We understand that CMS is requiring and will assume an oversight role to assure that covered studies meet the following standards:

- a. The principal purpose of the research study is to test whether a particular intervention potentially improves the participants' health outcomes.
- b. The research study is well supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
- c. The research study does not unjustifiably duplicate existing studies.
- d. The research study design is appropriate to answer the research question being asked in the study.
- e. The research study is sponsored by an organization or individual capable of executing the proposed study successfully.
- f. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 CFR Part 46. If a study is regulated by the Food and Drug Administration (FDA), it must be in compliance with 21 CFR parts 50 and 56.
- g. All aspects of the research study are conducted according to appropriate standards of scientific integrity (see <http://www.icmje.org>).
- h. The research study has a written protocol that clearly addresses, or incorporates by reference, the standards listed here as Medicare requirements for CED coverage.
- i. The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life threatening as defined in 21 CFR § 312.81(a) and the patient has no other viable treatment options.
- j. The clinical research study is registered on the ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject.
- k. The research study protocol specifies the method and timing of public release of all prespecified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned to be published in a peer reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors (<http://www.icmje.org>).*
- l. The research study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria effect enrollment of these populations, and a plan for the retention and reporting of said populations on the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.
- m. The research study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

Consistent with section 1142 of the Social Security Act, AHRQ supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

*We understand that any outcomes data provided for reconsideration of this decision would need to be submitted to CMS within an appropriate timeframe to allow adequate review by CMS within the three year expiration of CED.

Sincerely,

A handwritten signature in black ink, appearing to read 'J. Slutsky', with a long horizontal flourish extending to the right.

Jean R. Slutsky

Director, Center for Outcomes and Evidence