

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 144	Date: August 3, 2012
	Change Request 7836

SUBJECT: Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP)

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to inform contractors that effective for claims with dates of service on or after June 8, 2012, Medicare will only allow coverage of TENS for CLBP defined for this decision as pain for more than 3 months and not a manifestation of a clearly defined and generally recognizable primary disease entity, when the patient is enrolled in an approved clinical study under coverage with evidence development (CED).

EFFECTIVE DATE: June 8, 2012

IMPLEMENTATION DATE: January 7, 2013

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-Only One Per Row.

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	1/Table of Contents
N	1/160.27/Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP)

III. FUNDING:

For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:

No additional funding will be provided by CMS; Contractors activities are to be carried out with their operating budgets

For Medicare Administrative Contractors (MACs):

The Medicare Administrative contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC statement of Work. The contractor is not obliged to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

**Unless otherwise specified, the effective date is the date of service.*

Attachment - Business Requirements

Pub. 100-03	Transmittal: 144	Date: August 3, 2012	Change Request: 7836
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SUBJECT: Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP)

Effective Date: June 8, 2012

Implementation Date: January 7, 2013

I. GENERAL INFORMATION

A. Background: In 2010, the Therapeutic and Technology Assessment Subcommittee of the American Academy of Neurology (AAN) published a report finding transcutaneous electrical nerve stimulation (TENS) ineffective for chronic low back pain (CLBP). The Centers for Medicare and Medicaid Services (CMS) internally initiated a new national coverage determination (NCD) after the AAN published report and reviewed all the available evidence on the use of TENS for the treatment of CLBP.

Medicare has the following four NCDs pertaining to various uses of TENS that were developed before the CMS adoption of an evidence based and publicly transparent paradigm for coverage decisions.

- Transcutaneous Electrical Nerve Stimulation (TENS) for Acute Post-Operative Pain (10.2)
- Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy (160.7.1)
- Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation (NMES) (160.13)
- Transcutaneous Electrical Nerve Stimulators (TENS) (280.13) Please note, section 280.13 has been removed from the NCD manual and incorporated into NCD 160.27

Thus the evidentiary basis is unclear for historic coverage. TENS has been historically thought to relieve chronic pain but the current evidence base refutes this assertion when applied to TENS for CLBP. Since TENS falls within the durable medical equipment (DME) benefit, Medicare coverage results in purchase after a brief initial rental period, even if the patient soon develops a subsequent tolerance to the TENS effect.

B. Policy: After careful consideration, effective for claims with dates of service on or after, June 8, 2012, CMS believes the evidence is inadequate to support coverage of TENS for CLBP as reasonable and necessary. CMS appreciates the significant burden of CLBP on the beneficiary population, which may lead to frustration on the part of patients, their treating practitioners and their caregivers. However, this frustration should not be the underlying reason for coverage of an item or service in circumstances where treatments are not known to be beneficial. To date, we do not believe the existing evidence base supports the coverage of TENS for CLBP. Therefore, Medicare will only allow coverage of TENS for CLBP defined for this decision as pain for more than 3 months and not a manifestation of a clearly defined and generally recognizable primary disease entity, when the patient is enrolled in an approved clinical study under coverage with evidence development (CED).

NOTE: CED coverage expires three years from the effective date of this CR, June 8, 2015.

NOTE: Contractors shall accept the inclusion of the KX modifier on the claim line(s) as an attestation by the provider of the service that documentation is on file verifying the patient has chronic low back pain (CLBP) defined as an episode of low back pain that has persisted for three months or longer; and that the CLBP is not a manifestation of a clearly defined and generally recognizable primary disease entity as described in the TENS coverage policy for CLBP in Pub 100-03. See Pub.100-04 for claims processing.

NOTE: Contractors should refer to the business requirements below as well as general clinical trial billing requirements at Pub. 100-03, chapter 1, section 310, and Pub. 100-04, chapter 32, section 69.

See Pub. 100-03, NCD Manual, chapter 1, section 160.27, for the TENS coverage policy for CLBP, and Pub. 100-04, Claims Processing Manual, chapter 20, section 30.1.2, for claims processing instructions.

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M M A C	F I M A C	C A I E R	R H I S	Shared-System Maintainers				OTHER
						F I S S	M C S	V M S	C W F		
7836-03.1	Effective for claims with dates of service on and after June 8, 2012, Medicare will only allow coverage with evidence development (CED) of transcutaneous electrical nerve stimulation (TENS) for chronic low back pain (CLBP) defined for this decision as an episode of low back pain that has persisted for three months or longer, and is not a manifestation of a clearly defined and generally recognizable primary disease entity. Refer to Pub 100-04 for detailed Business Requirements.		X			X	X				

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M M A C	F I M A C	C A I E R	R H I S	Shared-System Maintainers				OTHER
						F I S S	M C S	V M S	C W F		
7836-03.2	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and	X	X	X		X					

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I M A C	C A R I E R	R H H I S S	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
	include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.										

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements, use the box below: N/A

Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: For all other recommendations and supporting information, use this space: N/A

V. CONTACTS

Pre-Implementation Contact(s):

Brijet Burton (coverage), 410-786-7364, brijet.burton2@cms.hhs.gov, Wanda Belle (coverage), wanda.belle@cms.hhs.gov, Patti Brocato-Simons (coverage), patricia.brocato-simons@cms.hhs.gov; Cynthia Glover (Division of Practitioner Claims Processing), 410-786-2589, cynthia.glover@cms.hhs.gov, Felicia Rowe (DME, supplier claims processing), 410-786-5655 or felicia.rowe@cms.hhs.gov, and Bill Ruiz (institutional claims processing), 410-786-9283, william.ruiz@cms.hhs.gov.

Post-Implementation Contact(s):

Contact your Contracting Officer's Representative (COR) or Contractor Manager, as applicable.

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs)*, *Regional Home Health Intermediaries (RHHIs)*, and/or *Carriers*, use only one of the following statements:

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

Section B: For *Medicare Administrative Contractors (MACs)*, include the following statement:

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

Medicare National Coverage Determinations Manual

Chapter 1, Part 2 (Sections 90 – 160.26) Coverage Determinations

Table of Contents *(Rev.144, Issued: 08-03-12)*

160.27 – Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP)

160.27 – Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP)

(Rev.144, Issued: 08-03-12, Effective: 06-08-12, Implementation: 01-07-13)

The TENS is a type of electrical nerve stimulator that is employed to treat chronic intractable pain. This stimulator is attached to the surface of the patient’s skin over the peripheral nerve to be stimulated. It may be applied in a variety of settings (in the patient’s home, a physician’s office, or in an outpatient clinic). Payment for TENS may be made under the durable medical equipment benefit.

A. General

For the purposes of this decision chronic low back pain (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.*

B. Nationally Covered Indications

Effective June 8, 2012, the Centers for Medicare & Medicaid Services (CMS) will allow coverage for Transcutaneous Electrical Nerve Stimulation (TENS) for CLBP only when all of the following conditions are met.

In order to support additional research on the use of TENS for CLBP, we will cover this item under section 1862(a)(1)(E) of the Social Security Act (the Act) subject to all of the following conditions:

- 1. Coverage under this section expires three years after the publication of this decision on the CMS website.*
- 2. The beneficiary is enrolled in an approved clinical study meeting all of the requirements below. 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.*
 - i. Does the use of TENS provide clinically meaningful reduction in pain in Medicare beneficiaries with CLBP?*
 - ii. Does the use of TENS provide a clinically meaningful improvement of function in Medicare beneficiaries with CLBP?*
 - iii. 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.

The study must adhere to the following standards of scientific integrity and relevance to the Medicare population:

- 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.*

C. *Nationally Non-Covered Indications*

TENS is not reasonable and necessary for the treatment of CLBP under section 1862(a)(1)(A) of the Act.

D. *Other*

See §160.13 for an explanation of coverage of medically necessary supplies for the effective use of TENS. See §160.7.1 for an explanation of coverage for assessing patients suitability for electrical nerve stimulation therapy. See §10.2 for an explanation of coverage of transcutaneous electrical nerve stimulation (TENS) for acute post-operative pain. Please note, §280.13 Transcutaneous Electrical Nerve Stimulators (TENS) NCD has been removed from the NCD manual and incorporated into NCD 160.27

(This NCD last reviewed June 2012.)