

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 2605	Date: November 30,2012
	Change Request 7836

Transmittal 2511, dated August 3, 2012, is being rescinded and replaced by Transmittal 2605 dated November 30, 2012. The Claims Processing Manual has been revised to update the language to clarify that the specific conditions are referenced in the NCD Manual. All other information remains the same.

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	20/30.1.2/Transcutaneous Electrical Nerve Stimulator (TENS)

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. 100-04	Transmittal: 2605	Date: November 30, 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, 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	C A R I E R	R H R I	Shared- System Maintainers	OTHER		
						F I S S	M C S	V M S	C W F	
7836-04.1	Effective for claims with dates of service on and after June 8, 2012, Medicare will only allow TENS for CLBP defined for this decision as pain for more than 3 months not caused by recognized neurodegenerative (e.g. multiple sclerosis) disease, malignancy, or well-defined rheumatic disorders (except osteoarthritis) under coverage with evidence development (CED). See chapter 1, section 160.27 of the NCD Manual.		X			X	X			
7836-04.2	Contractors shall accept and process line items that include an appropriate TENS HCPCS code, at least one ICD-9 diagnosis code for CLBP (see attachment), and <u>all</u> of the following: <ul style="list-style-type: none"> Dates of service on or after June 8, 2012, TENS HCPCS code E0720 or E0730 Acceptable ICD-9/ICD-10 code (see attachments), Modifiers KX and Q0 ICD-9 code V70.7 – Examination of participant in clinical trial (for institutional claims only), and Condition code 30 – (for institutional claims only). 		X			X	X			
7836-04.3	Contractors shall deny TENS line items on claims when billed with a TENS code and at least one of the ICD-9 codes for CLBP (see attachment), if the conditions of requirement 7836.2 are not met.		X			X	X			
7836-04.4	Contractors shall deny line items identified in requirements 7836.3 using the following remittance		X			X				

II. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I	C A R I E R	R H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
7836-04.8	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 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.	X	X		X	X					

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.burton@cms.hhs.gov, Wanda Belle (coverage), wanda.belle@cms.hhs.gov, Patti Brocato-Simons (coverage), patricia.brocatosimons@cms.hhs.gov; Cynthia Glover (Division of Practitioner Claims Processing), 410-786-2589, cynthia.glover@cms.hhs.gov, Diana Motsiopoulos (DME, supplier claims processing), 410-786-3379 or diana.motsiopoulos@cms.hhs.gov, and Bill Ruiz (institutional claims processing), 410-786-9283, william.ruiz@cmes.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.

Attachments

The list of ICD- 9 codes to be included in this decision would be:

- 353.4 Lumbosacral root lesions, not elsewhere classified
- 720.2 Sacroiliitis, not elsewhere classified
- 721.3 Lumbosacral spondylosis without myelopathy
- 721.42 Thoracic or lumbar spondylosis with myelopathy – lumbar region
- 722.10 Lumbar intervertebral disc without myelopathy
- 722.52 Lumbosacral intervertebral disc
- 722.73 Intervertebral disc disorder myelopathy – lumbar region
- 722.83 Post laminectomy syndrome – lumbar region
- 722.93 Other and unspecified disc disorders, lumbar region
- 724.02 Spinal stenosis, lumbar region without neurogenic claudication
- 724.03 Spinal stenosis, lumbar region with neurogenic claudication
- 724.2 Lumbago
- 724.3 Sciatica
- 724.4 Thoracic or lumbosacral neuritis or radiculitis, unspecified, radicular syndrome of lower extremities
- 738.4 Acquired spondylolisthesis
- 739.3 Non-allopathetic lesions NEC (not elsewhere classified) – lumbar region
- 756.11 Spondylosis, lumbosacral region
- 756.12 Spondylolisthesis
- 805.4 Fracture of vertebral column without mention of spinal cord injury, lumbar, closed
- 806.4 Fracture of vertebral column with mention of spinal cord injury, lumbar, closed
- 846.0 Sprains and strains of sacroiliac region – lumbosacral (joint) (ligament)
- 846.1 Sprains and strains of sacroiliac ligament
- 847.2 Sprains and strains of other and unspecified parts of back, lumbar
- 953.2 Injury to nerve roots and spinal plexus, lumbar root

The list of ICD-10 codes to be included in this decision would be:

M40.36 Flatback syndrome, lumbar
M40.37 Flatback syndrome, lumbosacral
M40.46 Postural lordosis, lumbar region
M40.47 Postural lordosis, lumbosacral region
M40.56 Lordosis, unspecified, lumbar region
M40.57 Lordosis, unspecified, lumbosacral region
M41.26 Other idiopathic scoliosis, lumbar region
M41.27 Other idiopathic scoliosis, lumbosacral region
M41.56 Other secondary scoliosis, lumbar region
M41.57 Other secondary scoliosis, lumbosacral region
M42.16 Adult osteochondrosis of spine, lumbar region
M42.17 Adult osteochondrosis of spine, lumbosacral region
M43.06 Spondylolysis, lumbar region
M43.07 Spondylolysis, lumbosacral region
M43.16 Spondylolysthesis, lumbar region
M43.17 Spondylolysthesis, lumbosacral region
M43.26 Fusion of spine, lumbar region
M43.27 Fusion of spine, lumbosacral region
M43.5X6 Other recurrent vertebral dislocation, lumbar region
M43.5X7 Other recurrent vertebral dislocation, lumbosacral region
M43.8X6 Other specified deforming dorsopathies, lumbar region
M43.8X7 Other specified deforming dorsopathies, lumbosacral region
M47.16 Other spondylosis with myelopathy, lumbar region
M47.17 Other spondylosis with myelopathy, lumbosacral region
M47.26 Other spondylosis with radiculopathy, lumbar region
M47.27 Other spondylosis with radiculopathy, lumbosacral region
M47.816 Spondylosis without myelopathy or radiculopathy, lumbar region
M47.817 Spondylosis without myelopathy or radiculopathy, lumbosacral region
M47.896 Other spondylosis, lumbar region
M47.897 Other spondylosis, lumbosacral region
M48.06 Spinal stenosis, lumbar region
M48.07 Spinal stenosis, lumbosacral region
M48.16 Ankylosing hyperostosis, lumbar region
M48.17 Ankylosing hyperostosis, lumbosacral region
M48.26 Kissing spine, lumbar region
M48.27 Kissing spine, lumbosacral region
M48.36 Traumatic spondyloarthropathy, lumbar region
M48.37 Traumatic spondyloarthropathy, lumbosacral region
M48.8X6 Other specified spondylopathies, lumbar region
M48.8X7 Other specified spondylopathies, lumbosacral region
M51.06 Intervertebral disc disorder with myelopathy, lumbar region
M51.07 Intervertebral disc disorder with myelopathy, lumbosacral region
M51.16 Intervertebral disc disorder with radiculopathy, lumbar region
M51.17 Intervertebral disc disorder with radiculopathy, lumbosacral region
M51.26 Other intervertebral disc displacement, lumbar region
M51.27 Other intervertebral disc displacement, lumbosacral region
M51.36 Other intervertebral disc degeneration, lumbar region
M51.37 Other intervertebral disc degeneration, lumbosacral region
M51.46 Schmorl's nodes, lumbar region
M51.47 Schmorl's nodes, lumbosacral region
M51.86 Other intervertebral disc disorders, lumbar region
M51.87 Other intervertebral disc disorders, lumbosacral region
M53.2X6 Spinal instabilities, lumbar region

M53.2X7 Spinal instabilities, lumbosacral region
M53.86 Other specified dorsopathies, lumbar region
M53.87 Other specified dorsopathies, lumbosacral region
M54.16 Radiculopathy, lumbar region
M54.17 Radiculopathy, lumbosacral region
M54.30 – M54.32 Sciatica
M54.40 – M54.42 Lumbago with sciatica
M54.5 Low back pain
S32.0 (including S32.000- S32.059) Fracture of lumbar vertebrae
S33.0 Traumatic rupture of lumbar intervertebral disc
S33.10-S33.14 Subluxation and dislocation of lumbar vertebra
S33.5 Sprain of ligaments of lumbar spine
S33.6 Sprain of sacroiliac joint
S34.21 Injury of nerve root of lumbar spine
S34.22 Injury of nerve root of sacral spine
S39.002 Unspecified injury of muscle, fascia and tendon of the lower back
S39.012 Strain of muscle, fascia and tendon of the lower back
S30.022 Laceration of muscle, fascia and tendon of the lower back
S30.092 Other injury of muscle, fascia and tendon of the lower back

30.1.2 - Transcutaneous Electrical Nerve Stimulator (TENS)

(Rev.2605, Issued: 11-30-12, Effective: 06-08-12, Implementation: 01-07-13)

In order to permit an attending physician time to determine whether the purchase of a TENS is medically appropriate for a particular patient, contractors pay 10 percent of the purchase price of the item for each of 2 months. The purchase price and payment for maintenance and servicing are determined under the same rules as any other frequently purchased item, except that there is no reduction in the allowed amount for purchase due to the two months rental.

Effective June 8, 2012, CMS will allow coverage for TENS use in the treatment of chronic low back pain (CLBP) only under specific conditions which are described in the NCD Manual, Pub. 100-03, chapter 1 Section 160.27.