DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

News Flash –When billing Medicare, Home Health Agencies (HHAs) must use the individual National Provider Identifier (NPI) of the physician who orders/refers services, not the NPI of the physician's group practice. If an HHA asks for your NPI, be sure to provide your individual NPI. Don't know your individual NPI? You may verify your NPI on the NPI Registry on the CMS website.

MLN Matters® Number: MM7836 Revised

Related Change Request (CR) #: CR 7836

Related CR Release Date: November 30, 2012

Effective Date: June 8, 2012

Related CR Transmittal #: R2605CP and R149NCD

Implementation Date: January 7, 2013

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

Note: This article was revised on December 4, 2012, to reflect a revised CR7836, issued on November 30, 2012. In this article, the CR transmittal numbers, release date, and the Web address for accessing CR7836 have been revised. All other information remains the same.

Provider Types Affected

This MLN Matters® Article is intended for providers and suppliers that submit claims to Medicare contractors (carriers, Regional Home Health Intermediaries (RHHIs), and Durable Medical Equipment Medicare Administrative Contractors (DME MACs)) for Transcutaneous Electrical Nerve Stimulation (TENS) services provided to Medicare beneficiaries.

What You Need to Know

This article is based on Change Request (CR) 7836 which informs providers and suppliers that the Centers for Medicare & Medicaid Services (CMS) is revising the coverage for TENS for Chronic Low Back Pain (CLBP) effective for claims with dates of service on or after June 8, 2012. See the *Key Points* section of this article for specific coverage rules and review the lists of ICD- 9 and ICD-10 codes attached to the official instruction CR7836.

Background

In 2010, the Therapeutic and Technology Assessment Subcommittee of the American Academy of Neurology (AAN) published a report finding TENS ineffective for CLBP. 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 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. Those four NCDs are:

- 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); and
- 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

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.

Key Points

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. Thus, effective for claims with dates of service on and after June 8, 2012, Medicare will only allow coverage of TENS for CLBP defined for this decision as pain for 3 months or longer 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.

Examples of clearly defined and recognizable primary disease entities: neurodegenerative (e.g. multiple sclerosis) disease, malignancy, or well-defined rheumatic disorders (except osteoarthritis).

Medicare contractors will accept and process line items that include an appropriate TENS HCPCS code, at least one ICD-9 diagnosis code for CLBP (see list of ICD-9 codes attached to CR7836), and **all** of the following:

- Date of service on or after June 8, 2012;
- Modifiers KX and Q0;
- ICD-9 code V70.7 - Examination of participant in clinical trial (for institutional claims only);
- Condition code 30 - (for institutional claims only)
- An acceptable ICD-9 code; and
- An acceptable ICD-10 code upon implementation (see list of ICD-10 codes attached to CR7836).

Medicare contractors will deny TENS line items on claims when billed with a TENS code and at least one of the ICD-9 or ICD-10 codes for CLBP (see attachments to transmittal R2605CP of CR7836 at http://www.cms.hhs.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2605CP.pdf), if the conditions of requirement listed above are not met. When Medicare denies such claims for not containing the requisite ICD-9 (or later ICD-10) code, your remittance advice will reflect the following messages:

- Group Code CO;
- Claim Adjustment Reason Code B5 (Coverage/program guidelines were not met or were exceeded.); and
- Remittance Advice Remark Code N386 (This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.

Medicare will pay for allowed TENS for CLBP based on the DME fee schedule.

All of the following conditions must be met for coverage of TENS for CLBP:

CLBP is defined as:

- An episode of low back pain that has persisted for three months or longer; and
- Is not the 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. Certain systemic diseases, e.g. rheumatoid arthritis, multiple sclerosis etc, manifest many debilitating symptoms of which low back pain is not the primary focus. CMS believes that the appropriate management of these types of diseases is guided by a systematic strategy aimed at the underlying causes. While TENS may infrequently be used adjunctively in managing the symptoms of these diseases, it is clearly not the primary therapeutic approach.

The patient is enrolled in an approved clinical study that addresses 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 a 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 provide a clinically meaningful reduction in 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 also adhere to standards of scientific integrity and relevance to the Medicare population and those standards are part of Section 160.27. You may read the entire set of parameters in the official instruction attached to transmittal R149NCD of CR7836. That transmittal is available at http://www.cms.hhs.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R149NCD.pdf on the CMS website.

Additional Information

The official instruction, CR 7836, issued to your Medicare Carrier, RHHI or DME MAC regarding this change via two transmittals. The first updates the NCD Manual and it is available at http://www.cms.hhs.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R149NCD.pdf on the CMS website. The other transmittal updates the "Medicare Claims Processing Manual" and it is available at http://www.cms.hhs.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2605CP.pdf on the CMS website.

If you have any questions, please contact your carrier, RHHI, or DME MAC at their toll-free number, which may be found at http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html on the CMS website.