INSTRUCTIONS FOR USE

This Policy Guideline is applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates for health care services submitted on CMS 1500 forms and, when specified, to those billed on UB04 forms (CMS 1450), or their electronic comparative. The information presented in this Policy Guideline is believed to be accurate and current as of the date of publication.

This Policy Guideline provides assistance in administering health benefits. All reviewers must first identify member eligibility, any federal or state regulatory requirements, Centers for Medicare and Medicaid Services (CMS) policy, the member specific benefit plan coverage, and individual provider contracts prior to use of this Policy Guideline. When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document may differ greatly from the standard benefit plan upon which this Policy Guideline is based. In the event of a conflict, the member specific benefit plan document supersedes this Policy Guideline. Other Policies and Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary.

UnitedHealthcare follows Medicare coverage guidelines and regularly updates its Medicare Advantage Policy Guidelines to comply with changes in CMS policy. UnitedHealthcare encourages physicians and other healthcare professionals to keep current with any CMS policy changes and/or billing requirements by referring to the CMS or your local carrier website regularly. Physicians and other healthcare professionals can sign up for regular distributions for policy or regulatory changes directly from CMS and/or your local carrier. This Policy Guideline is provided for informational purposes. It does not constitute medical advice.

POLICY SUMMARY

Overview

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 (a physician’s office, in the patient’s home, or in an outpatient clinic). Payment for TENS may be made under the durable medical equipment benefit.
For the purposes of this decision, chronic low back pain (CLBP) is defined 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. 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.

Guidelines
Nationally Covered Indications
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:

- Coverage under this section expires three years after the publication of this decision on the CMS website.
- 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.
- Does the use of TENS provide clinically meaningful reduction in pain in Medicare beneficiaries with CLBP?
- Does the use of TENS provide a clinically meaningful improvement of function in Medicare beneficiaries with CLBP?
- 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:
  - 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.
  - The principal purpose of the research study is to test whether a particular intervention potentially improves the participants’ health outcomes.
  - The research study is sponsored by an organization or individual capable of executing the proposed study successfully.
  - The research study does not unjustifiably duplicate existing studies.
  - The research study design is appropriate to answer the research question being asked in the study.
  - 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.
  - All aspects of the research study are conducted according to appropriate standards of scientific integrity (see http://www.icmje.org).
  - The research study has a written protocol that clearly addresses, or incorporates by reference, the standards listed here as Medicare requirements for CED coverage.
  - 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.
  - 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.
  - 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).
  - 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.
  - 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.
Nationally Non-Covered Indications
TENS is not reasonable and necessary for the treatment of CLBP under section 1862(a) (1)(A) of the Act.

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.

Non-Medical Necessity Coverage and Payment Rules
For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. "reasonable and necessary").

Transcutaneous electrical nerve stimulation equipment is covered under the Durable Medical Equipment benefit. In order for a beneficiary's equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

For an item addressed in this policy to be covered by Medicare, a written signed and dated order must be received by the supplier prior to delivery of the item. If the supplier delivers the item prior to receipt of a written order, it will be denied as noncovered. If the written order is not obtained prior to delivery, payment will not be made for that item even if a written order is subsequently obtained. If a similar item is subsequently provided by an unrelated supplier who has obtained a written order prior to delivery, it will be eligible for coverage.

During the rental of a TENS unit, supplies for the unit are included in the rental allowance; there is no additional allowance for electrodes, lead wires, batteries, etc. If a TENS unit (E0720 or E0730) is purchased, the allowance includes lead wires and one month's supply of electrodes, conductive paste or gel (if needed), and batteries.

Refer to the COVERAGE INDICATIONS, LIMITATIONS, AND/OR MEDICAL NECESSITY section of the LCD for additional information about coverage criteria and associated documentation.

Affordable Care Act (ACA) 6407 Requirements
ACA 6407 contains provisions that are applicable to specified items in this policy. In this policy the specified items are:

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>E0720</td>
<td>Transcutaneous electrical nerve stimulation (TENS) device, two lead, localized stimulation</td>
</tr>
<tr>
<td>E0730</td>
<td>Transcutaneous electrical nerve stimulation (TENS) device, four or more leads, for multiple nerve stimulation</td>
</tr>
<tr>
<td>E0731</td>
<td>Form fitting conductive garment for delivery of tens or nmes (with conductive fibers separated from the patient's skin by layers of fabric)</td>
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Face-to-Face Visit Requirements
As a condition for payment, Section 6407 of the Affordable Care Act (ACA) requires that a physician (MD, DO or DPM), physician assistant (PA), nurse practitioner (NP) or clinical nurse specialist (CNS) has had a face-to-face examination with the beneficiary that meets all of the following requirements:

- The treating physician must have an in-person examination with the beneficiary within the six (6) months prior to the date of the WOPD.
- This examination must document that the beneficiary was evaluated and/or treated for a condition that supports the need for the item(s) of DME ordered.

A new face-to-face examination is required each time a new prescription for one of the specified items is ordered. A new prescription is required by Medicare:

- For all claims for purchases or initial rentals.
- When there is a change in the prescription for the accessory, supply, drug, etc.
- If a local coverage determination (LCD) requires periodic prescription renewal (i.e., policy requires a new prescription on a scheduled or periodic basis)
- When an item is replaced
- When there is a change in the supplier
• When required by state law

The first bullet, "For all claims for purchases or initial rentals", includes all claims for payment of purchases and initial rentals for items not originally covered (reimbursed) by Medicare Part B. Claims for items obtained outside of Medicare Part B, e.g. from another payer prior to Medicare participation (including Medicare Advantage plans), are considered to be new initial claims for Medicare payment purposes.

**Prescription Requirements**

A WOPD is a standard Medicare Detailed Written Order, which must be completed, including the prescribing physician's signature and signature date, and must be in the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) supplier's possession BEFORE the item is delivered. The WOPD must include all of the items below:

- Beneficiary's name,
- Physician's Name
- Date of the order and the start date, if start date is different from the date of the order
- Detailed description of the item(s)
- The prescribing practitioner's National Provider Identifier (NPI),
- The signature of the ordering practitioner
- Signature date

For any of the specified items provided on a periodic basis, including drugs, the written order must include, in addition to the above:

- Item(s) to be dispensed
- Dosage or concentration, if applicable
- Route of Administration, if applicable
- Frequency of use
- Duration of infusion, if applicable
- Quantity to be dispensed
- Number of refills, if applicable

Note that prescriptions for these specified DME items require the National Provider Identifier to be included on the prescription. Prescriptions for other DMEPOS items do not have this NPI requirement. Suppliers should pay particular attention to orders that include a mix of items, to assure that these ACA order requirements are met.

**Date and Timing Requirements**

There are specific date and timing requirements:

- The date of the face-to-face examination must be on or before the date of the written order (prescription) and may be no older than 6 months prior to the prescription date.
- The date of the face-to-face examination must be on or before the date of delivery for the item(s) prescribed.
- The date of the written order must be on or before the date of delivery.
- The DMEPOS supplier must have documentation of both the face-to-face visit and the completed WOPD in their file prior to the delivery of these items.

A date stamp (or similar) is required which clearly indicates the supplier's date of receipt of both the face-to-face record and the completed WOPD with the prescribing physician's signature and signature date. It is recommended that both documents be separately date-stamped to avoid any confusion regarding the receipt date of these documents.

**Claim Denial**

Claims for the specified items subject to ACA 6407 that do not meet the requirements specified above will be denied as statutorily noncovered – failed to meet statutory requirements.

If the supplier delivers the item prior to receipt of a written order, it will be denied as statutorily noncovered. If the written order is not obtained prior to delivery, payment will not be made for that item even if a written order is subsequently obtained. If a similar item is subsequently provided by an unrelated supplier who has obtained a written order prior to delivery, it will be eligible for coverage.

**Coding Guidelines**

A transcutaneous electrical nerve stimulator (TENS) (E0720, E0730) is a device which utilizes electrical current delivered through electrodes placed on the surface of the skin to decrease the patient's perception of pain by inhibiting the transmission of afferent pain nerve impulses and/or stimulating the release of endorphins. A TENS unit must be distinguished from other electrical stimulators (e.g., neuromuscular stimulators) which are used to directly stimulate muscles and/or motor nerves.
A TENS supply allowance (A4595) includes electrodes (any type), conductive paste or gel (if needed, depending on the type of electrode), tape or other adhesive (if needed, depending on the type of electrode), adhesive remover, skin preparation materials, batteries (9 volt or AA, single use or rechargeable), and a battery charger (if rechargeable batteries are used).

Codes A4556 (Electrodes, [e.g., apnea monitor], per pair), A4558 (Conductive paste or gel), and A4630 (Replacement batteries, medically necessary TENS owned by patient) are not valid for claim submission. A4595 should be used instead.

For code A4557, one unit of service is for lead wires going to two electrodes. If all the lead wires of a 4 lead TENS unit needed to be replaced, billing would be for two units of service.

There should be no billing and there will be no separate allowance for replacement electrodes (A4556), conductive paste or gel (A4558), replacement batteries (A4630), or a battery charger used with a TENS unit.

Other supplies, including but not limited to the following, will not be separately allowed: adapters (snap, banana, alligator, tab, button, clip), belt clips, adhesive remover, additional connecting cable for lead wires, carrying pouches, or covers.

**APPLICABLE CODES**

The following list(s) of codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

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<tr>
<td>A4556</td>
<td>Electrodes (e.g., apnea monitor), per pair (Bundled/excluded code except for HH and DME)</td>
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<tr>
<td>A4557</td>
<td>Lead wires (e.g., apnea monitor), per pair (Bundled/excluded code except for HH and DME)</td>
</tr>
<tr>
<td>A4558</td>
<td>Conductive gel or paste, for use with electrical device (e.g., TENS, NMES), per oz (Bundled/excluded code except for HH and DME)</td>
</tr>
<tr>
<td>A4595</td>
<td>Electrical stimulator supplies, 2 lead, per month, (e.g., TENS, NMES)</td>
</tr>
<tr>
<td>A4630</td>
<td>Replacement batteries, medically necessary, transcutaneous electrical stimulator, owned by patient</td>
</tr>
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<td>E0720</td>
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**ICD-10 Diagnosis Codes**

NCD 160.27 ICD-10
Dx Coding.xls

**QUESTIONS AND ANSWERS**

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<th>Q:</th>
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<tr>
<td>1</td>
<td>Is TENS for chronic low back pain (CLBP) covered by CMS?</td>
<td>Only if the beneficiary is enrolled in an approved clinical study meeting all of the requirements within the NCD 160.27. Currently there are no CMS approved clinical studies.</td>
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**REFERENCES**

**CMS National Coverage Determinations (NCDs)**

NCD 160.27 Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP)
Reference NCDs: **NCD 10.2 Transcutaneous Electrical Nerve Stimulation (TENS) for Acute Post-Operative Pain; NCD 160.7.1 Assessing Patient’s Suitability for Electrical Nerve Stimulation Therapy**

### CMS Local Coverage Determinations (LCDs)

<table>
<thead>
<tr>
<th>LCD</th>
<th>DME</th>
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<tr>
<td>L33802 (Transcutaneous Electrical Nerve Stimulators (TENS))</td>
<td>CGS: AL, AR, CO, ID, IL, FL, GA, KY, LA, MI, MN, MS, NC, NM, OH, OK, PR, SC, TN, TX, VA, VI, WI, WV Noridian: AK, AS, AZ, CA, CT, DC, DE, GU, HI, IA, ID, KS, MA, MD, ME, MO, MP, MT, ND, NE, NH, NJ, NV, NY, OR, PA, RI, SD, UT, VT, WA, WI, WV</td>
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### CMS Articles

<table>
<thead>
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<th>Article</th>
<th>DME</th>
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<tr>
<td>A52520 (Transcutaneous Electrical Nerve Stimulators (TENS) - Policy Article - Effective October 2015)</td>
<td>CGS: AL, AR, CO, ID, IL, FL, GA, KY, LA, MI, MN, MS, NC, NM, OH, OK, PR, SC, TN, TX, VA, VI, WI, WV Noridian: AK, AS, AZ, CA, CT, DC, DE, GU, HI, IA, ID, KS, MA, MD, ME, MO, MP, MT, ND, NE, NH, NJ, NV, NY, OR, PA, RI, SD, UT, VT, WA, WI, WV</td>
</tr>
</tbody>
</table>

### CMS Benefit Policy Manual

**Chapter 15; § 110 Durable Medical Equipment - General**

### CMS Claims Processing Manual

**Chapter 20; § 30.1.2 Transcutaneous Electrical Nerve Stimulator (TENS)**

### CMS Transmittals

**Transmittal 1388, Change Request 8691, Dated 05/23/2014 (ICD-10 Conversion/Coding Infrastructure Revisions/ICD-9 Updates to National Coverage Determinations (NCDs)--Maintenance CR)**

**Transmittal 2511, Change Request 7836, Dated 08/03/2012 (Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP))**

**Transmittal 2605, Change Request 7836, Dated 11/30/2012 (Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP))**

### UnitedHealthcare Commercial Policies

**Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation**

### MLN Matters

**Article MM7836, Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP)**

### Others

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

### GUIDELINE HISTORY/REVISION INFORMATION

<table>
<thead>
<tr>
<th>Date</th>
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<tr>
<td>05/10/2017</td>
<td>• Annual review</td>
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