Transcutaneous Electrical Nerve Stimulators (TENS)

Adopted from National Government Services website

For any item to be covered by The Health Plan, it must:

1. Be eligible for a defined Medicare or The Health Plan benefit category
2. Be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member
3. Meet all other applicable Medicare and/or The Health Plan statutory and regulatory requirements

For the items addressed in this medical policy, the criteria for "reasonable and necessary" are defined by the following indications and limitations of coverage and/or medical necessity. Please refer to individual product lines certificates of coverage for possible exclusions of benefit.

For an item to be covered by The Health Plan, the supplier must receive a written, signed, and dated order before a claim is submitted to The Health Plan. If the supplier bills for an item addressed in this policy without first receiving the completed order, the item will be denied as not reasonable and necessary.

Suppliers are to follow The Health Plan requirements for precertification, as applicable.

TENS and the conductive garment (E0731) require precertification and physician face-to-face.

Any request above what is allowed in coverage guidelines will require precertification.

<table>
<thead>
<tr>
<th>CMS National Coverage Policy</th>
<th>CMS Publication 100-3 Medicare National Coverage Determinations Manual, Chapter 1, Sections 280.1, 280.7</th>
</tr>
</thead>
<tbody>
<tr>
<td>DME Region LCD Covers</td>
<td>Jurisdiction B</td>
</tr>
<tr>
<td>Revision/Review Effective Date</td>
<td>For services performed on or after 03/01/15</td>
</tr>
<tr>
<td></td>
<td>Revised: 04/01/17, 05/01/16, 1/1/14, 10/02/14</td>
</tr>
<tr>
<td>The Health Plan</td>
<td>Will follow Oversight Region B-C Coverage Determination posted on the CGS website unless otherwise indicated in sections of this policy, contractual agreement, or benefit plan document.</td>
</tr>
<tr>
<td></td>
<td>West Virginia Medicaid plans will follow Medicare Coverage Guidelines</td>
</tr>
</tbody>
</table>

DESCRIPTION

A TENS works by using electrical stimulation of the skin to relieve pain by interfering with the neural transmission of signals from underlying pain receptors.

COVERAGE GUIDELINES

A face-to-face must be done before dispensing a TENS unit or conductive garment.
TENS is covered for acute postoperative pain. Coverage is limited to 30 days (one month’s rental) from the day of surgery. Payment will be made only as a rental.

TENS is covered for chronic, intractable pain other than chronic low back pain when all of the following criteria must be met:

1. The pain must have been present for at least three months
2. Other appropriate treatment modalities must have been tried and failed.
   a. Failed medication
   b. Failed pain relieving modalities such as heat, ice, therapy etc.
3. Does not fall under one of the noncovered indications
4. If a Four leads is being requested the ordering physician must indicate if there has been a failure of a 2-lead TENS unit, or it is for use across a joint, large area of pain requiring 4 leads, or if adipose tissue interferes with conduction.

TENS therapy for chronic pain that does not meet these criteria will be denied as not meeting coverage guidelines.

When used for the treatment of chronic, intractable pain, other than chronic low back pain, the TENS unit must be used by the beneficiary on a trial basis for a minimum of one month (30 days), but not to exceed two months. The trial period will be paid as a rental. The trial period must be monitored by the physician to determine the effectiveness of the TENS unit in modulating the pain. For coverage of a purchase, the physician must determine that the member is likely to derive significant therapeutic benefit from continuous use of the unit over a long period of time.

COVERAGE OF TENSTM FOR CHRONIC LOW BACK PAIN (CLBP)

TENS therapy for CLBP is only covered for Medicare members when both of the following criteria are met:

1. The Medicare beneficiary is enrolled in an approved clinical study that meets all of the requirements set out in NCD §160.27 (CMS Internet Only Manual 100-3, Chapter 1). Refer to NGS or CGS links below for more information, and
2. The beneficiary has one of the following ICD-10 diagnoses found at: https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33802&ContrID=140

TENS used for CLBP does not require a trial rental period or an assessment of effectiveness by the treating physician. Upon the enrollment into an approved study, the TENS is eligible for purchase.

Use of Interferential Current Therapy devices- must be coded E0730 and must meet the PDAC guidelines to be coded as a TENS device- see billing guidelines.

COVERAGE OF CONDUCTIVE GARMENT (E0731)

A conductive garment (E0731) used with a TENS unit is rarely reasonable and necessary, but is covered only if all of the following conditions are met:

1. It has been prescribed by the treating physician for use in delivering covered TENS treatment; and
2. One of the medical indications outlined below is met:
   1. The member cannot manage without the conductive garment because
      1. There is such a large area or so many sites to be stimulated and;
      2. The stimulation would have to be delivered so frequently that it is not feasible to use conventional electrodes, adhesive tapes, and lead wires and;
      3. The member cannot manage without the conductive garment for the treatment of chronic intractable pain because the areas or sites to be stimulated are inaccessible with the use of conventional electrodes, adhesive tapes, and lead wires and;
      4. The member has a documented medical condition, such as skin problems, that preclude the application of conventional electrodes, adhesive tapes, and lead wires and;
      5. The member requires electrical stimulation beneath a cast to treat chronic intractable pain.

A conductive garment is not covered for use with a TENS device during the trial period unless:
   1. The member has a documented skin problem prior to the start of the trial period and;
   2. The TENS is medically necessary for the beneficiary.

If the criteria above are not met for E0731, it will be denied as not meeting coverage guidelines.

REPAIR AND REPLACEMENT
Follows reasonable useful lifetime guidelines.

NONCOVERAGE STATEMENT
A TENS unit is not covered for the treatment of acute pain (less than three months duration) other than for postoperative pain.

A TENS unit is not covered for the following diagnoses:
   a. Headache
   b. Visceral abdominal pain
   c. Pelvic pain
   d. Temporomandibular joint (TMJ) pain
   e. Chronic low back pain unless meeting updated coverage documentation

Effective 1/1/14, The Health Plan will no longer covers TENS UNITS for chronic low back pain per adoption of CMS policy effective in local LCD 10/2013 and other national payor policies. Must be part of a CMS clinical trial for coverage with DX of CLBP.

The Cefaly device is not covered, as it is considered precautionary, and must be coded A9270.

Physical Vascular Therapy devices such as Bemer are not covered and cannot be billed with E codes.

West Virginia Medicaid does not cover the conductive garment (E0731)

CODING INFORMATION
CPT/HCPCS codes: The appearance of a code in this section does not necessarily indicate coverage.

HCPCS MODIFIERS
TRANSCUTANEOUS ELECTRICAL NERVE STIMULATORS (TENS)

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>EY</td>
<td>NO PHYSICIAN OR OTHER LICENSED HEALTH CARE PROVIDER ORDER FOR THIS ITEM OR SERVICE</td>
</tr>
<tr>
<td>GA</td>
<td>WAIVER OF LIABILITY STATEMENT ISSUED AS REQUIRED BY PAYOR POLICY</td>
</tr>
<tr>
<td>GZ</td>
<td>ITEM OR SERVICE EXPECTED TO BE DENIED AS NOT REASONABLE AND NECESSARY</td>
</tr>
<tr>
<td>KX</td>
<td>REQUIREMENT SPECIFIED IN THE MEDICAL POLICY HAVE BEEN MET</td>
</tr>
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</table>

**HCPCS CODES**

**EQUIPMENT**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A9270</td>
<td>NON COVERED ITEM</td>
</tr>
<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>
</tr>
</tbody>
</table>

**SUPPLIES**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A4557</td>
<td>LEAD WIRES, (E.G., APNEA MONITOR), PER PAIR</td>
</tr>
<tr>
<td>A4595</td>
<td>ELECTRICAL STIMULATOR SUPPLIES, 2 LEAD, PER MONTH, (E.G. TENS, NMES)</td>
</tr>
</tbody>
</table>

Except for diagnoses indicating chronic low back pain found on the link listed previously, there are no specific diagnoses and ICD-10 codes that indicate medical necessity.

**DOCUMENTATION REQUIREMENTS**

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider. “ It is expected that the member’s medical records will reflect the need for the care provided. The member’s medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other health care professionals and test reports.

This documentation must be available upon request.

Medicare has made changes to its requirements for dispensing orders, detailed written orders, and proof of delivery. The Health Plan will require the following:
1. Physician order. Order must include the following:
   a. Member’s name
   b. Date
   c. Order must include any specific feature of the base code and every addition requested. The medical record must contain the information that supports the request for each item, and must be submitted with the precertification, if the item requires precertification, or with the claim, if no precertification was required
   d. Order must include diagnosis code
   e. Physician signature - with date. Date stamps are not appropriate
2. There must be documentation in the supplier’s records to support the medical necessity for the device. This information but must be available upon request per The Health Plan policy.
3. Proof of delivery to be kept on file by the provider of the item.
4. If templates or forms are submitted, (e.g. A Medicare Certificate of Medical Necessity, and /or a provider created form), The Health Plan reserves the right to request the medical record that may include, but not limited to, the physician office notes, hospital and nursing facility records, home health records.

   Note: Template provider forms, prescriptions, and attestation letters are not considered part of the medical record, even if signed by the ordering physician.

A Certificate of Medical Necessity (CMN), which has been completed, signed and dated by the treating physician, must be kept on file by the supplier and made available upon request. The CMN may act as a substitute for a written order if it contains all the required elements of an order. The CMN for TENS is CMS Form 848 (DME Form 06.03B). The initial claim must include an electronic copy of the CMN.

A CMN is not needed for a TENS trial.

**TENS UNIT PROVIDED WHILE MEMBER IN A PART A COVERED STAY**

Reimbursement for TENS provided to a member while the member is covered in a Part A facility is based on specific contract information with the individual facility, and whether or not the device is intended for use while the member is in the facility.

**BILLING GUIDELINES**

TENS unit can be a purchase rather than a rental for diagnosis other than post operative pain in which case the TENS unit can be a 30-day rental, as long as trial period has been done in inpatient or outpatient setting.

A 4-lead TENS unit may be used with either two leads or four leads, depending on the characteristics of the member’s pain. If it is ordered for use with four leads, the medical record must document why two leads are insufficient to meet the member’s needs.

During a rental period, supplies are not separately billable from the unit 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.
TRANSCUTANEOUS ELECTRICAL NERVE STIMULATORS (TENS)

Quantities of supplies greater than those described in the policy as the usual maximum amounts, in the absence of documentation clearly explaining the medical necessity of the excess quantities, will be denied as not reasonable and necessary.

A claim for code E0731 must be accompanied by the brand name and model number of the conductive garment. Documentation supporting the medical necessity for the E0731 must be kept in the supplier’s files and be available upon request.

When billing for quantities of supplies greater than those described in the policy as the usual maximum amounts, there must be clear documentation in the member’s medical records corroborating the medical necessity of this amount. The patient’s medical records that corroborate the order and any additional documentation that pertains to the medical necessity of items and quantities billed must be provided upon request.

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.

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.

**Interferential Current (IFC) Therapy** is a form of electrotherapy in which two currents are applied and “crossed” resulting in a different frequency at the interference (crossing) point. This approach allows a higher frequency current to be applied to the skin to overcome skin resistance with a lower frequency current created in the underlying tissue. Lower frequency currents are thought to produce stronger effects with less discomfort.

IFC devices can be configured to allow use for pain relief like transcutaneous electrical nerve stimulators (TENS).

When used as TENS:

**E0730 (TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION (TENS) DEVICE, FOUR OR MORE LEADS, FOR MULTIPLE NERVE STIMULATION)**

Supplies (leads, electrodes, batteries, etc.) used with IFC devices are billed using the existing TENS supply codes. 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).

Not otherwise classified (NOC) or miscellaneous codes must not be used to bill for IFC devices or for supplies used with an IFC device.

**DISPENSING SUPPLIES**

Separate allowance will be made for replacement supplies when they are reasonable and necessary and are used with a covered TENS. Usual maximum utilization is:

- Two TENS leads - a maximum of one unit of A4595 per month
- Four TENS leads - a maximum of two units of A4595 per month

If the use of the TENS unit is less than daily, the frequency of billing for the TENS supply code should be reduced proportionally.

Replacement of lead wires (A4557) more often than every 12 months would rarely be reasonable and necessary.

Requests for supplies greater than the allowable requires precertification.

The Health Plan is following Medicare’s guidelines in regards to DME items provided on a recurring basis. Suppliers are reminded that they are not to automatically dispense supplies according to allowable limits. Suppliers are required to reorder supplies based on actual usage of each member. There must be a specific request for the supplies from the member prior to dispensing the supplies. Contact is to be no sooner than 14 calendar days. Supplies should not be shipped/delivered no sooner than 10 days prior to end of usage.

**KX, GA, and GZ MODIFIERS**

Suppliers may submit a claim with a KX modifier only if all the criteria for that item are met.

If coverage criteria are not met, the GA or GZ modifier must be used. When there is an expectation of a medical denial, suppliers must enter the GA modifier on the claim line if they have obtained a properly executed Advance Beneficiary Notice (ABN) or the GZ modifier if they have not obtained a valid ABN.

**ADVANCED BENEFICIARY NOTICE**

The Health Plan expects providers to follow the Medicare policy on ABN across all Medicare, Medicaid, and Commercial plans.

**NOTE**: Providers may be held financially responsible if they furnish the above items without notifying the member, verbally and in writing, that the specific service being provided is not covered. This must be done prior to the dispensing of the device. The provider must submit the waiver or Advanced Beneficiary Notification (ABN) to The Health Plan with the claim showing the member agreed to pay for the device. Generalized statements on waivers or ABN are not acceptable.

**PRICING, DATA ANALYSIS, AND CODING (PDAC)**

The Health Plan has implemented use of Medicare’s PDAC contractor for review of authorizations. Please refer to PDAC website for the appropriate product classification list. [dmepdac.com](http://dmepdac.com/)
**MEDICARE DEFINITIONS AND DESCRIPTION**

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.

The **Cefaly Device** is a transcutaneous electrical nerve stimulator that is applied to the forehead using a self-adhesive electrode positioned bilaterally over the upper branches of the trigeminal nerve. It is used for the prophylactic treatment of episodic migraine headaches.

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**INTERNET LINKS AND SOURCES**


The Health Plan Provider Procedural Manual. Payment Voucher, Section 14, Page 11


(CMS Program Integrity Manual, Internet-Only Manual, CMS Pub. 100-8, Chapter 5, Section 5.2.6)


INTERNAL REFERENCE ONLY: aetna.com/cpb/medical/data/1_99/0011.html-