


MEDICAL POLICY	Transcutaneous Electrical Nerve Stimulators (TENS) and Related Supplies (All Lines of Business Except Medicare)
Effective Date: 10/1/2021	Medical Policy Number: 85
 10/1/2021	Technology Assessment Committee Approved Date: 7/10; 1/15; 7/15 Medical Policy Committee Approved Date: 7/05 ; 7/06; 3/07; 3/09; 1/10; 8/12; 11/12; 4/13; 4/14; 4/16; 5/17; 6/18; 1/19; 2/2020; 4/2021; 9/2021
Medical Officer	Date

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:

All lines of business except Medicare

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

DOCUMENTATION REQUIREMENTS

In order to determine the medical necessity of the request, the following documentation must be provided at the time of the request. Medical records to include documentation of all of the following:

- For all claims for TENS and related supplies there must be information in the medical record demonstrating that the coverage criteria are met.
- For acute post-operative pain, there must be information about:
 - the date of surgery
 - the nature of the surgery
 - the location and severity of the pain
- For chronic pain other than low back pain, there must be information in the medical record describing:

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- The location of the pain
- The severity of the pain
- The duration of time the patient has had the pain
- The presumed etiology of the pain
- Prior treatment and results of that treatment
- Reevaluation of the patient at the end of the trial period, must include:
 - How often the patient used the TENS unit
 - The typical duration of use each time
 - The results (effectiveness of therapy)
- For CLBP there must be information in the medical record describing the qualifying diagnosis

POLICY CRITERIA

This policy is based on the following Centers for Medicare & Medicaid Services (CMS) guidance documents:

- National Coverage Determination (NCDs):
 - 160.7.1. Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy¹
 - 10.2: Transcutaneous Electrical Nerve Stimulation (TENS) for Acute Post-Operative Pain.²
 - 160.27: Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP).³
 - 160.13: Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation (NMES).⁴
- Local Coverage Determination (LCD) LCD L33802: Transcutaneous Electrical Nerve Stimulators (TENS).⁵
- Local Coverage Article (LCA): A52520: Transcutaneous Electrical Nerve Stimulators (TENS) - Policy Article.⁶

This CMS guidance was identified as of the last policy review date on 2/18/2021.

Acute Post-Operative Pain

- I. The use of transcutaneous electrical nerve stimulation (TENS) may be considered **medically necessary and covered** for the relief of acute post-operative pain for a maximum of 30 days from the day of surgery.
- II. The use of a TENS unit is considered **not medically necessary and not covered** for acute pain (less than three months duration) other than for post-operative pain.

Chronic Pain Other than Low Back Pain

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- III. The use of TENS may be considered **medically necessary and covered** for chronic (at least 3 months), intractable pain other than chronic low back pain when **all** of the following criteria are met (A. – B.):
- A. Documentation that age-appropriate activities of daily living are moderately or severely impacted (see [Policy Guidelines](#) for definition of activities of daily living); **and**
 - B. Pain has failed to improve after at least 3 months of conservative care (e.g. rest, ice, NSAIDs, or physical therapy).
- IV. The use of TENS therapy is considered **not medically necessary and not covered** for chronic pain if the criterion III. above is not met and for conditions in which etiology of pain has been determined to be unresponsive, including but not limited to:
- A. Chronic headache
 - B. Visceral abdominal pain
 - C. Pelvic pain
 - D. Temporomandibular joint [TMJ] pain)
 - E. Knee osteoarthritis

Note: The TENS unit must be used by the patient on a trial basis for a minimum of one month (30 days), but not to exceed two months. The trial period must be monitored by the physician to determine the effectiveness of the TENS unit in modulating the pain. Please see [Billing Guidelines](#) section below for more information on the trial period.

Chronic Low Back Pain (CLBP)

- V. The use of TENS is considered **medically necessary and covered** for chronic low back pain (CLBP) when the patient has one of the diagnosis codes listed in the ICD-10 Codes that Support Medical Necessity, which are listed in the LCA [A52520](#).

Note: The presence of an ICD-10 code listed in the LCA is not sufficient by itself to assure coverage.

- VI. The use of TENS therapy is considered **not medically necessary and not covered** for CLBP if the criterion V. above is not met.

Supplies Used in the Delivery of TENS

- VII. For the purposes of assessing a patient's suitability for a TENS device, a conductive garment is considered **medically necessary and covered** for use with a TENS device during the trial period when both of the following criteria are met:
- A. The patient has a documented skin problem prior to the start of the trial period; **and**
 - B. The TENS is reasonable and necessary for the patient.

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Note: Please see criterion IV. above for what constitutes a trial for assessing patient's suitability for TENS therapy.

- VIII. A form-fitting conductive garment (and medically necessary related supplies) may be considered **medically necessary and covered** when **both** of the following criteria (A. and B.) are met:
- A. It has been prescribed by a physician for use in delivering covered TENS or NMES treatment; **and**
 - B. **One** of the medical indications outlined below is met (1. – 4.):
 - 1. The patient cannot manage without the conductive garment because:
 - a. There is such a large area or so many sites to be stimulated; **and**
 - b. The stimulation would have to be delivered so frequently that it is not feasible to use conventional electrodes, adhesive tapes, and lead wires; **or**
 - 2. The patient 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; **or**
 - 3. The patient has a documented medical condition, such as skin problems, that preclude the application of conventional electrodes, adhesive tapes, and lead wires; **or**
 - 4. The patient requires electrical stimulation beneath a cast to treat chronic intractable pain.
- IX. A conductive garment is considered **not medically necessary and not covered** for use with a TENS device when the above criteria (VII. or VIII.) are not met.
- X. Remote electrical neuromodulation (REN) devices (e.g. Nerivio REN device) are **considered investigational and not covered** for treating migraines.

POLICY GUIDELINES

Definitions

Activities of daily living: The activities of daily living (ADLs) is a term used to describe essential skills that are required to independently care for oneself. Examples may include, but are not limited to, the following:

- Ambulating
- Feeding
- Dressing
- Personal hygiene
- Transportation and shopping
- Meal preparation

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- Housecleaning and home maintenance

General Requirements for Chronic Pain and CLBP

The physician ordering the TENS unit and related supplies must be the treating physician for the disease or condition justifying the need for the TENS unit.

A 4-lead TENS unit may be used with either 2 leads or 4 leads, depending on the characteristics of the patient's pain. If it is ordered for use with 4 leads, the medical record must document why 2 leads are insufficient to meet the patient's needs.

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

TENS for CLBP

TENS used to treat CLBP is provided under limited coverage. Reimbursement is only available for beneficiaries who are enrolled in an approved clinical trial. CMS maintains a list of policies that require study participation as a condition of coverage on the CMS web site. For each policy the approved studies are listed and a link provided to the study on the clinicaltrials.gov web site. The clinicaltrials.gov identifier number required on each claim is listed on this site.

Definition of Necessary and Reasonable

Although an item may be classified as DME, it may not be covered in every instance. Coverage in a particular case is subject to the requirement that the equipment be necessary and reasonable for treatment of an illness or injury, or to improve the functioning of a malformed body member. These considerations will bar payment for equipment which cannot reasonably be expected to perform a therapeutic function in an individual case or will permit only partial therapeutic function in an individual case or will permit only partial payment when the type of equipment furnished substantially exceeds that required for the treatment of the illness or injury involved.

Reasonableness of the Equipment

Even though an item of DME may serve a useful medical purpose, the DME MAC or A/B MAC (A) must also consider to what extent, if any, it would be reasonable for the Medicare program to pay for the item prescribed. The following considerations should enter into the determination of reasonableness:

1. Would the expense of the item to the program be clearly disproportionate to the therapeutic benefits which could ordinarily be derived from use of the equipment?
2. Is the item substantially more costly than a medically appropriate and realistically feasible alternative pattern of care?

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3. Does the item serve essentially the same purpose as equipment already available to the patient?

Payment Consistent With What is Necessary and Reasonable

Where a claim is filed for equipment containing features of an aesthetic nature or features of a medical nature which are not required by the patient’s condition or where there exists a reasonably feasible and medically appropriate alternative pattern of care which is less costly than the equipment furnished, the amount payable is based on the rate for the equipment or alternative treatment which meets the patient’s medical needs.

Payment for Additional Expenses for Deluxe Features

The payment amount for a given service or item, whether rented or purchased, must be consistent with what is reasonable and medically necessary to serve the intended purpose (see section above). Additional expenses for "deluxe" features, or items that are rented or purchased for aesthetic reasons or added convenience, do not meet the reasonableness test. Thus, where a service or item is medically necessary and covered under the Medicare program, and the patient wishes to obtain such deluxe features, the payment is based upon the payment amount for the kind of service or item normally used to meet the intended purpose (i.e., the standard item.) Usually this is the least costly item.

BILLING GUIDELINES

Acute Post-Operative Pain

When the TENS device is used for acute post-operative pain, payment of a TENS device will be made only as a rental. Coverage is limited to 30 days (one month's rental) from the day of surgery.

General Requirements for Chronic Pain and CLBP (Trial Period)

When used for the treatment of chronic pain other than low back pain the TENS unit must be used by the patient 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. For coverage of a purchase, the physician must determine that the patient is likely to derive significant therapeutic benefit from continuous use of the unit over a long period of time.

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

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:

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- 2 **TENS** leads - a maximum of one unit of A4595 per month
- 4 **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.

Reimbursement for supplies is contingent upon use with a covered **TENS** unit. Claims for **TENS** supplies provided when there is no covered **TENS** unit will be denied as not reasonable and necessary.

Effective for claims with dates of service on or after June 8, 2012 supplies provided for use with a previously covered **TENS** unit used for CLBP (not as part of an approved study) are not eligible for reimbursement. These supply claims will be denied as not reasonable and necessary.

Coding Guidelines

A transcutaneous electrical nerve stimulator (TENS) (E0720, E0730) is a device that 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 to the DME MAC. 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.

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Suppliers should contact the Pricing, Data Analysis and Coding (PDAC) Contractor for guidance on the correct coding of these items.

Additional Billing Guidelines

The use of TENS in the clinic for treatment of all covered medical indications is anticipated to be brief since it is reasonable to assume that most patients can self-treat or apply this modality with caregiver assistance in their home once training has been completed. The medical record must clearly indicate medical necessity rationale for ongoing use of TENS in the clinic. The following is a clinical guide for appropriate coding for TENS application and instruction:

TENS Application

CPT® 64550 - Initial application including patient/caregiver instruction in the use of TENS.

Unattended Application

HCPCS G0283 - Subsequent application of TENS following initial application. Presence of a qualified clinician is not necessary for the entire treatment session.

TENS Application During Exercise

CPT® 97110 or 97032 - The medical record must clearly indicate medical necessity for the rare use of TENS while the patient is performing therapeutic exercises. This service requires the constant presence of a qualified clinician for the entire treatment session. When time-based coding requirements are met, then either 97110 or 97032 may be billed, but not both.

TENS Education

CPT® 97535 - Additional patient and/or caregiver instruction is needed for TENS application beyond the initial instruction. This service requires the constant presence of a qualified clinician for the entire treatment session.

CPT/HCPCS CODES

All Lines of Business Except Medicare	
No Prior Authorization Required	
<u>NOTE:</u> The appearance of a code in this section does not necessarily indicate coverage.	
TENS APPLICATION AND INSTRUCTION:	
97014	Application of a modality to 1 or more areas; electrical stimulation (unattended)
97032	Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes

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97110	Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility
97535	Self-care/home management training (eg, activities of daily living (ADL) and compensatory training, meal preparation, safety procedures, and instructions in use of assistive technology devices/adaptive equipment) direct one-on-one contact, each 15 minutes
G0283	Therapeutic procedures to improve respiratory function, other than described by g0237, one on one, face to face, per 15 minutes (includes monitoring)
EQUIPMENT:	
E0720	Transcutaneous electrical nerve stimulation (tens) device, two lead, localized stimulation
E0730	Transcutaneous electrical nerve stimulation (tens) device, four or more leads, for multiple nerve stimulation
E0731	Form fitting conductive garment for delivery of tens or nmes (with conductive fibers separated from the patient's skin by layers of fabric)
E0745	Neuromuscular stimulator, electronic shock unit
SUPPLIES:	
A4556	Electrodes, (e.g., apnea monitor), per pair
A4557	Lead wires, (e.g., apnea monitor), per pair
A4558	Conductive gel or paste, for use with electrical device (e.g., tens, nmes), per oz
A4595	Electrical stimulator supplies, 2 lead, per month, (e.g., tens, nmes)
A4630	Replacement batteries, medically necessary, transcutaneous electrical stimulator, owned by patient
Not Covered	
K1023	Distal transcutaneous electrical nerve stimulator, stimulates peripheral nerves of the upper arm

DESCRIPTION

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).

For the purposes of this medical policy 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.

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REVIEW OF THE EVIDENCE

TENS for Knee Osteoarthritis

A 2019 Hayes review (updated 2020) was conducted on safety and efficacy of TENS for knee osteoarthritis (KOA).⁷ A total of 13 randomized controlled trials (RCTs) were included in the review, 3 of which were double-blind, sham-controlled RCTs, 7 of which were single-blind, and 3 of which were open label. Five studies assessed TENS efficacy over Sham TENS. One poor-quality study found that treatment with TENS improved pain and function measures in adults with KOA over sham treatment. Two fair-quality studies and 2 poor-quality studies found no added benefit of TENS over sham TENS. Eleven studies compared TENS to another intervention, two of which (both rated poor-quality) found TENS to be more effective in improving KOA symptoms than other interventions. One fair-quality RCT and 3 poor-quality RCTs found no differences in outcomes with TENS versus other interventions. One fair-quality RCT and 2 poor-quality RCTs found mixed results, with some outcomes showing no differences, some showing inferiority and others showing superiority. Two poor-quality studies favored other interventions (manual therapy and laser therapy) over TENS. Hayes determined that the body of evidence pertaining to KOA and TENS was moderate in size and low in overall quality.

Hayes gave TENS to treat knee osteoarthritis in adults a D1 rating, stating that a moderate-size body of overall low-quality evidence suggests that TENS is safe, but does not offer any additional benefit relative to sham TENS.

Remote electrical neuromodulation (REN) devices

In 2021, Hayes published an evidence review on Nerivio (Theranica Bio-Electronics Ltd.) for the treatment of acute migraine episodes.⁸ The review included 7 studies, one RCT, one RCT plus 2 secondary analyses of its data, and 3 case series. One fair-quality RCT and one poor quality RCT found that Nerivio was a more effective pain management tool than sham treatment. Post hoc analyses of the poor-quality RCT found that Nerivio performed similarly to usual care. Three poor-quality case series reported most participants experienced pain relief of an unclear degree and smaller proportions experienced complete resolution when Nerivio was used to treat acute migraine episodes. One systematic review was also included in the review. The systematic review included 38 RCTs on neurostimulation for migraines, 2 of which addressed REN and found that Nerivio was associated with a greater proportion of patients achieving pain-free status at 2 hours follow up compared to sham. Limitations of trials and systematic reviews include the following: RCTs were of poor or fair quality and compared treatment to sham, rather than usual care; case series are retrospective, uncontrolled, and unblinded and are at high risk of bias; No studies reviewed adverse effects.

Hayes concluded, after reviewing both clinical studies and systematic reviews, that there is minimal support for using Nerivio for management of acute migraine episodes.

INSTRUCTIONS FOR USE

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Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days' notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

REFERENCES

1. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy (160.7.1). Effective: 6/19/2006. <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=63>. Accessed 2/28/2021.
2. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) 10.2. Transcutaneous Electrical Nerve Stimulation (TENS) for Acute Post-Operative Pain. Effective: 6/8/2012. Implementation Date: 1/7/2013 <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=145>. Accessed 2/28/2021.
3. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) 160.27. Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP). Effective: 6/8/2012. Implementation Date: 1/7/2013. <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=354>. Accessed 2/28/2021.
4. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation (NMES) (160.13). Effective: 7/14/1988 <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=151>. Accessed 2/28/2021.
5. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD): Transcutaneous Electrical Nerve Stimulators (TENS) (L33802). Effective: 1/1/2020.

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<https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33802>.

Accessed 2/28/2021.

6. Centers for Medicare & Medicaid Services. Local Coverage Article: Transcutaneous Electrical Nerve Stimulators (TENS) - Policy Article (A52520). Effective: 01/01/2020.

<https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52520>.

Accessed 2/28/2021.

7. Hayes. Transcutaneous Electrical Nerve Stimulation For Knee Osteoarthritis. Published 1/30/2019. Reviewed 3/25/2020. . <https://evidence.hayesinc.com/report/dir.tensknee4511>.

Accessed 3/11/2021.

8. Hayes. Nerivio (Theranica Bio-Electronics Ltd.) for Treatment of Acute Migraine Episodes. Published July 23, 2021. <https://evidence.hayesinc.com/report/eer.nerivio4838>. Accessed 9/21/2021.