

Transcutaneous Electrical Nerve Stimulation (TENS) Unit

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Introduction

Transcutaneous electrical nerve stimulation (TENS) units are addressed by this guideline.

Health Equity Consideration

Health equity is the highest level of health for all individuals; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which individuals are born, grow, live, work, and age. Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include the following: safe housing, transportation, and neighborhoods; racism, discrimination, and violence; education, job opportunities, and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

Criteria

2-Lead TENS Unit

A 2-lead TENS is considered medically necessary when **either**:

- The individual has acute post-operative pain and **both** of the following:
 - There have been 30 days or less since surgery.
 - The TENS unit will be used in addition to or in place of medication.
- The individual has chronic intractable pain other than low back pain and **all** of the following:
 - The pain has lasted at least three months.
 - Other standard treatments have been tried and failed.

4-Lead TENS

A 4-lead TENS unit is considered medically necessary when **either**:

- The individual has acute post-operative pain and **all** of the following:

- There have been 30 days or less since surgery.
- The TENS unit will be used in addition to or in place of medication.
- There is a medical reason why a 2-lead unit cannot meet the individual's needs.
- The individual has chronic intractable pain other than low back pain and **all** of the following:
 - The pain has lasted at least three months.
 - Other standard treatments have been tried and failed.
 - There is a medical reason why a 2-lead unit cannot meet the individual's needs.

Note: HCPCS A4595 should be used in place of A4630, as this code may be used for items other than TENS units. HCPCS A4595 includes electrodes, conductive paste or gel, tape or other adhesives, adhesive remover, skin preparation materials, batteries, and a battery charger.

Conductive Garment

A conductive garment used with a TENS unit is considered medically necessary if **both** of the following conditions are met:

- The garment has been prescribed by the treating practitioner for use in delivering covered TENS treatment
- There is a medical indication that precludes application of conventional electrodes, adhesive tapes, and lead wires including **any** of the following:
 - There is a large treatment area or many sites to be stimulated.
 - The individual has a documented medical condition, such as a skin condition.
 - The individual requires electrical stimulation beneath a cast to treat chronic intractable pain.

Additional Information

For acute post-operative:

- TENS is considered medically necessary for the treatment of acute post-operative pain. Coverage is limited to 30 days from the day of surgery. Payment will be made only as a rental.
- 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:

- The one month (30 day) trial period is required (see "Trial Period" below). Following a successful trial, the device may continue to be rented or may be purchased.
- TENS is medically necessary for chronic, intractable pain other than chronic low back pain when **all** of the following criteria are met:
 - The presumed etiology of pain is considered responsive to TENS therapy.
 - There must be information in the medical record describing:
 - The location of the pain.
 - The severity of the pain.
 - The duration of time the individual has had the pain.
 - The presumed etiology of the pain.
 - Prior treatment and results of that treatment.
 - The pain must have been present for at least three months.
 - Other appropriate treatment modalities must have been tried and failed.

Trial period

- The TENS unit must be used by the individual 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 treating practitioner to determine the effectiveness of the TENS unit in modulating the pain and functional levels.
- Reevaluation of the individual at the end of the trial period, must indicate:
 - How often the TENS unit was used.
 - The typical duration of use.
 - Effectiveness of therapy.
- For coverage of a purchase, the treating practitioner must determine that the individual is likely to derive significant therapeutic benefit from continuous use of the unit over a long period of time.
- A conductive garment is not covered for use with a TENS device during the trial period unless the individual has a documented skin problem prior to the start of the trial period, and the TENS is reasonable and necessary for the individual.

Special Considerations and Safety

- TENS should not be used in individuals who are pregnant, who have epilepsy, or who have electronic implants, such as a cardiac pacemaker, or implantable cardioverter defibrillator.
- Electrodes should not be placed over the eyes, transcerebrally, on the front of the neck, internally, over tumors, directly over the spine, or on damaged or infected skin.

Supplies

- During the rental of a TENS unit, supplies for the unit are included in the rental allowance; there is no additional allowance for items such as electrodes, lead wires, and batteries.
- If a TENS unit is purchased, separate allowance will be made for replacement supplies (HCPCS A4595) when they are reasonable and necessary and are used with a covered TENS.

Not Covered

- TENS therapy for chronic low back pain (CLBP) will be denied as not medically necessary due to insufficient evidence to support its use in the literature.

Evidence Discussion

A 2023 systematic review and meta analysis by DeJesus et al. examined 58 studies to evaluate the analgesic effects of TENS in individuals with chronic musculoskeletal pain and acute experimental pain. Thirty-four studies assessed pain intensity and 24 evaluated hyperalgesia, while temporal summation was assessed in only two studies. The meta analyses found that TENS was consistently favored over placebo, demonstrating reductions in primary and secondary hyperalgesia as well as decreases in pain intensity at rest and during movement. The review reported that studies involving musculoskeletal pain showed high level evidence for reductions in primary hyperalgesia, while other outcomes showed moderate evidence. Overall, the findings suggested that TENS produced analgesia by reducing both central and peripheral sensitization across varied pain conditions. However, the review was limited by heterogeneity among included trials, inconsistent assessment of key pain mechanisms, and a small subset of studies meeting inclusion criteria, which reduced the strength and generalizability of its conclusions.

A 2021 systematic review by Johnson et al. evaluated 381 randomized controlled trials (n= 24,532) and investigated the efficacy and safety of TENS for acute and chronic pain. The analysis showed that pain intensity was significantly lower during or immediately after TENS compared with placebo, with 91 trials involving 92 samples and 4,841 individuals. Additional comparisons demonstrated lower pain intensity relative to standard pharmacological and non-pharmacological care across 61 trials with 3,155 individuals. No serious adverse events were reported, and adverse effects were generally mild and similar to comparators. Limitations included imprecision caused by small sample sizes within contributing trials and inconsistent reporting of adverse events, which reduced certainty in some outcomes.

A 2020 systematic review and meta-analysis by Zhou et al. aimed to determine the analgesic efficacy and safety of TENS in post-operative pain after pulmonary surgery.

Ten studies were included in the analysis. The results indicated that the TENS group had lower pain intensity scores on the first five post-operative days compared with the placebo TENS group. Thus, the investigators concluded that TENS might be an effective supplementary analgesic regimen in multi-modal analgesia to decrease pain intensity after pulmonary surgery.

Shimoura et al. (2019) conducted a randomized controlled trial to investigate the effect of TENS on knee pain and physical function in knee osteoarthritis (OA). Fifty individuals with knee pain were randomly assigned to the TENS group (n=25) or the sham TENS group (n=25). Participants wore a TENS device behind the patella of the symptomatic knee. Participants in the sham TENS group utilized an inactive TENS device. TENS intervention significantly improved the walk distance and visual analog scale (VAS) score of the six-minute walk test (distance $p=0.015$; VAS $p=0.030$). No adverse events were noted with either group. Thus, the authors noted that TENS may be effective for long-distance walking in patients with pre-radiographic knee OA.

Wu et al. (2018) performed a systematic review and meta-analysis that compared the effectiveness of TENS to sham and other nerve stimulation therapies (NSTs) for the treatment of chronic back pain (CBP). CBP was defined as pain lasting greater than 12 weeks. Twelve randomized controlled trials (n=700) were included in the analysis and compared TENS to sham TENS and to other NSTs, such as electroacupuncture, percutaneous electrical nerve stimulation, and percutaneous neuromodulation therapy. The efficacy of TENS was similar to that of control treatment for providing pain relief ($P = 0.293$). Other types of NSTs were more effective than TENS in providing pain relief ($P = 0.017$); however, TENS was more effective than control (sham) treatment in improving functional disability only in patients with follow-up of less than six weeks ($P < 0.001$). There was no difference in functional disability outcomes between TENS and other NSTs. However, the difference in improvement of disability between TENS and other NSTs was not conclusive because only two studies were included in the analysis. The authors noted that additional randomized trials that compare the efficacy of TENS and other established treatment modalities were needed.

An analysis by the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology (AAN) (Dubinsky & Miyasaki, 2010) (reaffirmed 2021) stated that TENS is not recommended for the treatment of chronic low back pain based on the current evidence. In addition, AAN stated that TENS is "probably effective" in reducing diabetic peripheral neuropathy pain.

Codes addressed in this guideline

The inclusion of any code in this table does not imply that the code is under management or requires prior authorization. Refer to the applicable health plan for management details. Prior authorization of a code listed in this table is not a guarantee

of payment. The Certificate of Coverage or Evidence of Coverage policy outlines the terms and conditions of the member's health insurance policy.

HCPSC Code	Description
A4541	Monthly supplies for use of device coded at E0733
A4542	Supplies and accessories for external upper limb tremor stimulator of the peripheral nerves of the wrist
A4544	Electrode for external lower extremity nerve stimulator for restless legs syndrome
A4557	Lead wires, (e.g., apnea monitor), per pair
A4595	Electrical stimulator supplies, 2 lead, per month, (e.g., tens, nmes)
A4630	Replacement batteries, medically necessary, transcutaneous electrical stimulator, owned by patient.
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)

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