Transcutaneous Electrical Nerve Stimulation (TENS) Unit

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Introduction

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

Criteria

2-Lead TENS Unit

A 2-lead TENS (HCPCS E0720, A4557, A4595) is 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 (HCPCS E0730, A4557, A4595) is 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.

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Conductive Garment

A conductive garment (HCPCS E0731) used with a TENS unit is 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 medically necessary for 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.

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  - 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

Definitions

A **transcutaneous electrical nerve stimulation (TENS)** unit is a medical device that consists of a battery-operated unit that uses 2- or 4-lead electrodes applied to the skin or a conductive fabric garment to deliver low intensity stimulation for pain control. A high frequency stimulation (70 to 100 Hz) at a low intensity is delivered to stimulate large afferent nerve fibers which then inhibit the smaller nerve fibers at the spinal

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segmental level, which is known as the gate-control method of pain relief. This method of stimulation creates a "pins and needles" or vibratory sensation in the treatment area.

Evidence Discussion

Medical Background

The United States Food and Drug Administration (FDA) considers TENS devices to be Class II devices. As such, they are considered to be of moderate to high risk and require manufacturers to submit 510(k) premarket notification before marketing their products (FDA, 2021). Manufacturers with TENS devices available in the United States include: AUVON®, Belifu®, NURSAL®, Oxiline®, and TechCare®.

Literature Review

- 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). Twelve randomized controlled trials including 700 patients were included in the analysis. CBP was defined as pain lasting greater than 12 weeks. Included studies compared TENS to sham TENS and to other NSTs (including electroacupuncture, percutaneous electrical nerve stimulation, and percutaneous neuromodulation therapy). The primary outcome was the difference in the mean change in pain from baseline to after the intervention. The secondary outcome was the difference between groups in improvement of functional disability. 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 ($P = 0.017$). Transcutaneous electrical nerve stimulation 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. In summary, the authors concluded that TENS did not improve symptoms of lower back pain, but may have offered short-term improvement of functional disability. However, the difference in improvement of disability between TENS and other NSTs was not conclusive. The authors noted that additional randomized trials that compare the efficacy of TENS and other established treatment modalities were needed.
- Martimbianco et al. (2019) conducted a Cochrane review to evaluate the effectiveness of transcutaneous electrical nerve stimulation (TENS) compared with sham and other clinical interventions for the treatment of chronic neck pain. Seven randomized controlled trials with 651 individuals with chronic neck pain lasting greater than 12 weeks met inclusion criteria. The primary outcomes were pain, disability, and adverse events. The length of follow-up ranged from one week to six

months. The authors found very low-certainty evidence from two trials that TENS reduced neck pain at short-term follow-up (three months after treatment). None of the included studies reported on disability or adverse events. Thus, the authors reported insufficient evidence to support the use of TENS in individuals with chronic neck pain.

- A 2022 randomized controlled trial reported by Reichenbach and colleagues aimed to determine the effectiveness of TENS at relieving pain and improving physical function in individuals with knee osteoarthritis (OA). Two hundred twenty participants with knee osteoarthritis were randomized to three weeks of treatment with TENS (n=108) or placebo TENS (n=112). The primary endpoint was knee pain at the end of three weeks of treatment assessed with the Western Ontario and McMaster Universities Arthritis Index (WOMAC) pain subscale. Secondary outcome measures included WOMAC physical function subscale and safety outcomes. There was no difference between TENS and placebo TENS in WOMAC pain at the end of treatment (P=0.74) or throughout the trial duration (P=0.98). The occurrence of adverse events was similar across groups. No differences were observed in secondary outcomes. Thus, the authors found no difference between TENS and placebo TENS in WOMAC pain scores at the end of three weeks of treatment. The authors added that current clinical practice guidelines either made no recommendation for the use of TENS in knee OA treatment or recommended against its use, which aligned with the low quality of the available evidence.
- Shimoura et al. (2019) conducted a randomized controlled trial to investigate the effect of transcutaneous electrical nerve stimulation (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 included in the study were aged 50 years or older; Kellgren-Lawerence grades zero or one for one or both knees, evaluated using weight-bearing anteroposterior radiographs; and an average pain rating of 4 - 9 on a numeric rating scale (zero to ten points). Participants wore a TENS device behind the patella of the symptomatic knee. After baseline measurement, the TENS devices in the TENS group were turned on. Participants in the sham-TENS group utilized an inactive TENS device. The primary outcome measure was assessment of pain using the visual analog scale (VAS) after the stair climb test, Timed Up and Go (TUG) test, and the six-minute walk test (6MWT). Secondary outcomes included knee extensor strengths and the two-step test and stand-up test from the locomotive syndrome risk test. Follow-up assessment occurred after a 30-minute rest period while wearing the TENS device. TENS intervention significantly improved the walk distance and VAS score of the 6MWT (distance p=0.015; VAS p=0.030). No adverse events were noted with either group. The investigators found that use of TENS improved the VAS score for pain and the distance walked in the 6MWT for individuals with Kellgren-Lawrence grade 0 or 1 of the knee. Thus, the authors noted that TENS may be effective for long-distance walking in patients with pre-radiographic knee osteoarthritis.

- Johnson et al. (2015) performed a systematic review to evaluate TENS as a treatment for acute pain (defined as less than 12 weeks duration). The review included 19 studies (n=1,346) that compared TENS to placebo, no treatment, pharmacological interventions, or non-pharmacological interventions. The types of acute pain included: procedural pain (e.g., cervical laser treatment, venipuncture, screening flexible sigmoidoscopy), and non-procedural pain (e.g., postpartum uterine contractions, rib fractures). There was limited evidence that TENS reduced pain intensity over placebo when TENS was the sole treatment modality. However, the reduction in pain was inconsistent across studies and there was an insufficient number of participants to draw firm conclusions. Thus, the authors reported that the available evidence did not support TENS for the treatment of acute pain.
- Binny et al. (2019) conducted a systematic review to evaluate the efficacy of TENS for acute low back pain. The review included three randomized trials (n=192). The primary outcome measure was pain relief within two-weeks of administration assessed using the visual analogue scale (VAS). One low quality trial (n=63) provided low quality evidence that approximately 30 minutes of treatment with TENS in an emergency-care setting provided pain relief for moderate to severe acute low back pain compared with sham treatment. The other two included studies each administered a course of TENS over four to five weeks with inconclusive evidence. Moreover, there was limited data on adverse events or long term follow-up. In conclusion, the investigators found insufficient evidence supporting the effectiveness of TENS for acute low back pain. Additional larger, well-designed prospective studies were recommended to further evaluate TENS in this population.
- Li and Song (2017) performed a meta-analysis to evaluate the effectiveness and safety of transcutaneous electrical nerve stimulation (TENS) for pain control after total knee arthroplasty (TKA). Five randomized trials including 472 adult participants who had undergone unilateral TKA met the inclusion criteria. The intervention group received TENS after TKA, and the control group received a nonfunctional placebo TENS that provided no stimulus. Outcome measures included: visual analogue scale (VAS) scores in different periods, opioid consumption, length of stay, and post-operative complications. There were significant differences between groups in VAS after TKA at 12 hours ($P<0.005$), 24 hours ($P=0.008$), and 48 hours ($P=0.021$). Moreover, significant differences were found regarding opioid consumption at 12 hours ($P=0.000$), 24 hours ($P=0.005$), and 48 hours ($P=0.048$). In conclusion, the authors found that TENS significantly reduced pain and opioid consumption after TKA. In addition, there were fewer adverse effects in the TENS groups.
- In 2021, Cardinali and colleagues performed a systematic review to determine if the use of TENS as an adjunct to standard of care decreases pain and analgesic use and improves pulmonary function for post-cardiothoracic surgery patients. Five randomized controlled trials were included in the meta-analysis of pain at 24, 48, and 72 hours post-operatively. The primary outcome measures analyzed were visual analog scale (VAS) and pulmonary function data. The results of the study

demonstrated that TENS had a significant impact on VAS at rest (P<0.00001) and with coughing (P<0.0001). FEV1 improved after 72 hours (P<0.00001), as did forced vital capacity (P=0.01). In summary, the authors found that the addition of TENS therapy to multi-modal analgesia significantly decreased pain following cardiothoracic surgery, increased the recovery of pulmonary function, and decreased the use of analgesics

- A 2020 systematic review and meta-analysis (Zhou et al.) aimed to determine the analgesic efficacy and safety of transcutaneous electrical nerve stimulation (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 post-operative day (P=0.004), post-operative day two (P=0.002), post-operative day three (P=0.03), post-operative day four (P<0.001), and post-operative day five (P<0.001) 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
- Gibson et al. (2019) performed a Cochrane review to evaluate the effectiveness of TENS for the treatment of chronic pain of any origin (excluding headaches and migraines). Nine randomized controlled trials which assessed the effectiveness of TENS were included in the analysis. Primary outcomes included pain intensity and adverse effects. Secondary outcomes included: disability, health-related quality of life, analgesic medication use, and participant global impression of change. One review including five studies (n=207) reported a beneficial effect of TENS versus sham therapy at reducing pain intensity (P<0.001). However, the authors noted the evidence was of low quality due to significant methodological limitations. The authors reported a low quality of evidence and small number of participants included in the studies; and thus, the authors were unable to confidently state whether TENS is effective in relieving pain in individuals with chronic pain.
- A Cochrane review (Amatya et al., 2018) aimed to investigate the effectiveness and safety of non-pharmacological therapies for the management of chronic pain in multiple sclerosis (MS). The analysis included 10 randomized controlled trials with 565 participants. The authors reported a very low level of evidence for use of non-pharmacologic treatments such as TENS. In addition, the authors noted that more studies with robust methodologies and greater numbers of participants were needed to show the effect of this intervention for the management of chronic pain in MS.

Professional organizations/societies

- The 2022 Department of Veterans Affairs and Department of Defense Practice Guideline for the Diagnosis and Treatment of Low Back Pain determined that there was inconclusive evidence to support the use of TENS to treat low back pain
- 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.

- The 2021 American Academy of Orthopedic Surgeons Management of Osteoarthritis of the Knee (Non-Arthroplasty) Evidence-Based Guideline found limited evidence to recommend TENS to improve pain or function for individuals with knee osteoarthritis (OA). The recommendation was based upon three studies which found that TENS was effective in reducing pain associated with OA but not in improving function. Thus, additional research was recommended including larger randomized controlled trials to examine the long-term effectiveness of the intervention.

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.

HCPCS Code	Description
A4557	Lead wires, (e.g., apnea monitor), per pair
A4595	Electrical stimulator supplies, 2 lead, per month, (e.g., tens, nmes)
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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