Transcutaneous Electrical Nerve Stimulation Clinical Coverage Criteria

Overview

Transcutaneous electrical nerve stimulation (TENS) is the application of a mild electrical current to the cutaneous nerve fibers using surface electrodes. Stimulation is characterized by current, pulse width, and changes in frequency. The amplitude of the current is adjusted to just above or just below the sensory threshold. Duration of application varies from short time periods (e.g., 30 minutes) once to continuous stimulation. Duration of treatment can be days to months. TENS is used extensively for pain relief in various disorders and is distinguished from other electrical stimulators, e.g. neuromuscular stimulators, which are used to directly stimulate muscles and/or nerves.

Policy

This Policy applies to the following Fallon Health products:

☒ Commercial

☒ Medicare Advantage

☒ MassHealth ACO

☒ NaviCare

☒ PACE

Fallon Health follows guidance from the Centers for Medicare and Medicaid Services (CMS) for organization (coverage) determinations for Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and guidance in the Medicare manuals are the basis for coverage determinations. When there is no NCD, LCD, LCA or manual guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations.

Medicare has the following NCDs related to transcutaneous electrical nerve stimulation (TENS):

- NCD for Transcutaneous Electrical Nerve Stimulation (TENS) for Acute Post-Operative Pain (10.2)
- (NCD) for Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation (NMES) (160.13)
- NCD for Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP) (160.27)

NCD for Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP) (160.27) allowed for coverage of TENS for chronic low back pain when the plan member was enrolled in an approved clinical study under coverage with evidence development (CED) for three years, beginning on June 8, 2012 and ending June 8, 2015. At this time, TENS is not reasonable and necessary for the treatment of CLBP under section 1862(a)(1)(A) of the Act.

Noridian Healthcare Solutions, LLC is the DME MAC with jurisdiction in our service area. Noridian Healthcare Solutions, LLC has an LCD for Transcutaneous Electrical Nerve Stimulators (TENS) (L33802) and an LCA: Transcutaneous Electrical Nerve Stimulators (TENS) - Policy Article (A52520). (MCD search 02/09/2022).

For plan members enrolled in NaviCare, Fallon Health follows Medicare guidance for coverage determinations. In the event that there is no Medicare guidance or if the plan member does not meet medical necessity criteria in Medicare guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations for NaviCare members. Fallon Health's Clinical Coverage Criteria are developed in accordance with the definition of Medical Necessity in 130 CMR 450.204.

Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

Fallon Health covers TENS units and related supplies as an adjunct or alternative to the use of other medical treatments or services to treat (1) acute post-operative pain, or (2) chronic, intractable musculoskeletal or neuropathic pain, other than chronic low back pain.

Fallon Health requires a covered diagnosis for payment of TENS claims, please see the below list of ICD 10 codes. Prior authorization is not required but failure to bill within below guidelines or use of TENS for excluded diagnosis will deny. For all claims for TENS and related supplies, there must be documentation in the medical record demonstrating that the coverage criteria are met.

TENS units are initially covered as a rental for one or two months (depending on the condition). Effective with dates of service on or after January 1, 2020 a Standard Written Order (SWO) must be communicated to a supplier before billing for A TENS unit or TENS supplies. Someone other than the treating practitioner may complete the SWO, however the treating practitioner must review and sign the document. The term "treating practitioner" is defined as the one who is directly providing care to the plan member for the condition(s) related to the DMEPOS ordered. For plan members who meet criteria for continued coverage of TENS beyond the rental period, Fallon Health will cover the purchase of a TENS unit. The purchase of a TENS unit at the end of the rental period requires a new written order. The supplier may not submit a claim for the purchase of the TENS unit until they have the new written order for the purchase of the TENS unit on file TENS or related supplies are covered for the treatment of the following conditions when all of the related criteria are met.

Fallon Health Clinical Coverage Criteria
Fallon Health follows coverage criteria in Noridian Healthcare Solutions, LLC LCD for Transcutaneous Electrical Nerve Stimulators (TENS) (L33802) and LCA: Transcutaneous Electrical Nerve Stimulators (TENS) - Policy Article (A52520) for all plan members.

Policy References:
LCD link: **Transcutaneous Electrical Nerve Stimulators (TENS) (L33802)**
LCA link: **Transcutaneous Electrical Nerve Stimulators (TENS) - Policy Article (A52520)**

Documentation Reference:
LCA link: **Standard Documentation Requirements Policy Article (PA) (A55426)**

1. Acute post-operative pain
    - TENS is covered for acute post-operative pain. There must be documentation in the medical record demonstrating that the coverage criteria are met. For acute post-operative pain, documentation of all of the following is required:
        - Date of surgery
        - Nature of the surgery
        - Location and severity of the pain

- Coverage of TENS for acute post-operative pain is limited to 30 days (one month's rental) from the day of surgery.
- TENS for acute post-operative pain is covered as a rental only.
- When a TENS unit is rented, supplies for the unit are included in the rental allowance; there will be no additional allowance for electrodes, lead wires, batteries, etc.
- TENS is not covered for other types of acute pain, including but not limited to acute low back pain, procedural pain, labor pain, and primary dysmenorrhea.

2. Chronic, intractable pain, other than chronic low back pain (CLBP)*
    - TENS is covered for chronic, intractable pain other than CLBP when all of the following criteria are met:
        - The presumed etiology of the pain must be a type that is accepted as responding to TENS therapy. Examples of conditions for which TENS therapy is not considered to be reasonable and necessary are (not all-inclusive):
            - headache
            - visceral abdominal pain
            - pelvic pain
            - temporomandibular joint (TMJ) pain
        - The pain must have been present for at least three months.
        - Other appropriate treatment modalities must have been tried and failed.
    - When used for the treatment of chronic, intractable pain, the TENS unit must be used by the plan member on a trial basis for a minimum of one month (30 days), but not to exceed two months, to determine efficacy. The trial period will be covered as a rental. The trial period must be monitored by the treating physician to determine the effectiveness of the TENS unit in modulating pain. For coverage of a purchase, the treating practitioner must determine that the plan member is likely to derive significant therapeutic benefit from continuous use of the unit over a long period of time.
    - There must be documentation in the medical record demonstrating that the coverage criteria are met. For chronic, intractable pain, documentation of all of the following is required:
        - The location of the pain
        - The severity of the pain
        - The duration of time the beneficiary has had the pain
        - The presumed etiology of the pain
        - Prior treatment and results of that treatment
        - Reevaluation of the beneficiary at the end of the trial period, must indicate
            - How often the beneficiary used the TENS unit
            - The typical duration of use each time
            - The results (effectiveness of therapy)
    - When a TENS unit is rented, supplies for the unit are included in the rental allowance; there will be no additional allowance for electrodes, lead wires, batteries, etc.
    - TENS may be used with either 2 or 4 leads, depending on the characteristics of the patient's pain. If a 4-lead unit (2 channel) is ordered, the medical record must document why 2 leads are insufficient to meet the plan member's needs.

At any time, if the plan member's condition no longer requires TENS, or if the plan member is no longer benefitting from the use of the TENS device, coverage for the TENS unit will be discontinued by the treating physician.

* TENS for Chronic Low Back Pain (CLBP) will be denied as not medically necessary.

Replacement supplies for member-owned TENS
When the TENS unit has become the property of the plan member, Fallon Health will cover replacement supplies and lead wires for as long as the plan member's condition continues to require TENS and the plan member continues to benefit from the use of

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

For all supplies provided on a recurring basis, the supplier is required to have a written order from the treating physician on file (a written order for TENS supplies is valid for 12 months) and suppliers are required to contact the plan member prior to dispensing a refill of supplies to ensure that the items remain necessary and that existing supplies are approaching exhaustion. Suppliers may not dispense more than a 3-month quantity of supplies at any one time.

The following supplies are covered for eligible plan members:

1. Replacement lead wires (HCPCS code A4557) for a patient-owned TENS unit:
    - For a 2-lead TENS unit, one unit (i.e., one pair) of lead wires will be allowed per 12 months;
    - For a 4-lead TENS unit, when TENS is ordered for use with 4 leads, two units (i.e., two pairs) of lead wires will be allowed per 12 months.
    - For a 4-lead TENS unit, when TENS is ordered for use with 2 leads, one unit (i.e., one pair) of lead wires will be allowed per 12 months.
2. Replacement supplies (HCPCS code A4595) for a patient-owned TENS unit:
    - For a 2-lead TENS unit, one unit of electrical stimulator supplies will be allowed per month.
    - For a 4-lead TENS unit, when TENS is ordered for use with 4 leads, two units of electrical stimulator supplies will be allowed per month.
    - For a 4-lead TENS unit, when TENS is ordered for use with 2 leads, one unit of electrical stimulator supplies will be allowed per month.

HCPCS code 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).

HCPCS 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, HCPCS code A4595 should be used instead.

Conductive garments (HCPCS code E0731)
TENS is ordinarily delivered through the use of electrodes and lead wires. There may be times, however, where it might be medically necessary for certain patients receiving TENS treatment to use, as an alternative to conventional electrodes and lead wires, a form-fitting conductive garment. A form-fitting conductive garment, used with a TENS unit, is rarely medically necessary, but will be covered when the garment has been prescribed by the treating physician for use in delivering TENS treatment for one of the following medical indications:

- The patient cannot manage without the conductive garment because there is such large area or so many sites to be stimulated and the stimulation would have to be delivered so frequently that it is not feasible to use conventional electrodes and lead wires, or
- 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
- The patient has a documented medical condition such as skin problems that preclude the application of conventional electrodes and lead wires, or
- The patient requires electrical stimulation beneath a cast to treat chronic intractable pain.

A form-fitting conductive garment is not covered during the one-month trial period unless the patient has a documented skin problem prior to the start of the trial period and the use of such a garment is medically necessary for the member.

Exclusions

- Any use of TENS treatment for other conditions than outlined above.
- Devices which are not FDA approved for home use.
- Transcutaneous electrical joint stimulation devices (HCPCS code E0762) for the treatment of osteoarthritis or rheumatoid arthritis pain, because there is insufficient scientific evidence in the published peer-reviewed literature to support the use of electrical stimulation for these indications.
- TENS for motor-function disorders such as multiple sclerosis, acute or chronic headache, deep abdominal pain, pelvic pain, temporomandibular joint pain, because there is insufficient scientific evidence in the published peer-reviewed literature to support the use of TENS for these indications.
- Electrical stimulation for the treatment of chronic wounds (HCPCS code E0769), because there is insufficient scientific evidence in the published peer-reviewed literature on the safety of unsupervised electrical stimulation of wounds in the home.
- The Food and Drug Administration (FDA) has several product classifications for TENS devices, one of which is designated for TENS devices that may be sold over-the-counter (OTC). OTC TENS are identified with FDA product code NUH. OTC TENS are not considered durable medical equipment (DME). OTC TENS are not covered and are not reimbursable.

Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

HCPCS 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, HCPCS code A4595 should be used instead.

Code	Description
E0720	Transcutaneous electrical nerve stimulation (TENS) device, 2 lead, localized stimulation
E0730	Transcutaneous electrical nerve stimulation (TENS) device, 4 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)
A4557	Lead wires, per pair
A4595	Electrical stimulator supplies, 2 lead, per month (e.g., TENS, NMES)

Claims for TENS units and/or TENS supplies billed with an ICD-10-CM diagnosis code for chronic low back pain identified in the Noridian Healthcare Solutions, LLC LCA: Transcutaneous Electrical Nerve Stimulators (TENS) - Policy Article (A52520) will deny vendor liable.

References

1. Centers for Medicare & Medicaid Services (CMS) National Coverage Determination (NCD) for Transcutaneous Electrical Nerve Stimulation (TENS) for Acute Post-Operative Pain (10.2). Effective June 8, 2012.
2. Centers for Medicare & Medicaid Services (CMS) National Coverage Determination (NCD) for Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation (NMES) (160.13). Effective July 14, 1988.

3. Centers for Medicare & Medicaid Services (CMS) National Coverage Determination (NCD) for Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Lower Back Pain (CLBP) (160.27). Effective June 8, 2012.
4. Noridian Healthcare Solutions, LLC. Local Coverage Determination (LCD) for Transcutaneous Electrical Nerve Stimulators (TENS) L33802. Original Effective Date 10/01/2015. Revision Effective Date 11/20/2021. Available at: https://www.cms.gov/medicare-coverage-database/new-search/search.aspx. Accessed 02/09/2022.
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6. Wellington J. Noninvasive and alternative management of chronic low back pain (efficacy and outcomes). Neuromodulation. 2014 Oct;17 Suppl 2:24-30.
7. Kerai S, Saxena KN, Taneja B, Sehrawat L. Role of transcutaneous electrical nerve stimulation in post-operative analgesia. Indian J Anaesth. 2014 Jul;58(4):388-93.
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12. Gibson W, Wand BM, Meads C, Catley MJ, O'Connell NE. Transcutaneous electrical nerve stimulation (TENS) for chronic pain - an overview of Cochrane Reviews. Cochrane Database Syst Rev. 2019 Apr 3;4:CD011890.

Policy history

Origination date:	11/01/2000
Approval(s):	Utilization Management Committee: 11/1/2000, 12/2000, 06/01/2006 01/22/2013 Technology Assessment Sub-Committee: 06/2003 Technology Assessment Committee: 02/28/2006, 02/26/2014, 02/25/2015 (updated references, clarified policy language), 03/23/2016 (removed ICD-9 codes, updated references), 04/26/2017 (updated references), 05/15/2018 (updated references), 05/22/2019 (updated references) *02/09/2022 (Added clarifying language related to Medicare Advantage, NaviCare and PACE under policy section).*

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.