

## Electronic Cell-Signaling Treatment

An electronic cell-signaling treatment device is FDA-approved for the management and systematic relief of chronic pain, relaxation of muscle spasms, and increasing blood circulation. This device is similar to devices you use to perform Electrical Nerve Stimulation Therapy,<sup>1</sup> which Medicare covers as outlined in [National Coverage Determination \(NCD\): Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy \(160.7.1\)](#). However, Medicare doesn't cover the electronic cell-signaling treatment device.

We're aware of questionable billing of electronic cell-signaling treatment with the use of this device in combination with vitamin injections. This combination is often marketed as a treatment for pain, peripheral neuropathy, neuromuscular re-education, and other medical conditions. Medicare doesn't cover electronic cell-signaling treatment because it's considered experimental, medically unnecessary, and investigational.

Specifically, Medicare doesn't cover electronic cell-signaling treatment:

- For metabolic, peripheral, or multiple neuropathies because it isn't considered medically reasonable and necessary
- For neuropathies in patients with underlying systemic diseases because it's considered investigational
- With vitamin injections using the following injection codes because they don't meet our definition of reasonable and necessary covered drugs and biologicals: J1955, J3411, J3415, J3420, J3490

### What Medicare Covers

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Medicare covers services, drugs, and biologicals if they're reasonable and necessary for the diagnosis or treatment of your patient's illness or injury or to improve the functioning of a malformed body part. You must document the need for these services, drugs, and biologicals in your patient's medical records. If we request to see the records during the claims process, you must provide them.

Below is a discussion of devices and procedures that Medicare covers under certain circumstances. These coverage requirements don't include the electronic cell-signaling treatment device.

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<sup>1</sup>This broad category of nerve stimulators includes Transcutaneous Electrical Nerve Stimulation (TENS) and Percutaneous Electrical Nerve Stimulation (PENS), among others. While these types of devices are often covered when deemed medically reasonable and necessary, specific coverage criteria must be met and exclusions do apply. For example, NCD 160.7.1 states: "[I]t is inappropriate for a patient to visit his/her physician, physical therapist, or an outpatient clinic on a continuing basis for treatment of pain with electrical nerve stimulation ... Electrical nerve stimulation treatments furnished by a physician in his/her office, by a physical therapist or outpatient clinic are excluded from coverage by §1862(a)(1) of the Act."

## Peripheral Nerve Blocks

We consider peripheral nerve blocks medically reasonable and necessary for normally temporary medical conditions if 1 or more of these applies:

- You use peripheral nerve blocks diagnostically when a patient's pain appears to be due to a classic mononeuritis, but the neuro-diagnostic studies have failed to provide a structural explanation
- A patient's peripheral nerve injuries, entrapment, or other extremity trauma leads to complex regional pain syndrome
- You use selective peripheral nerve block diagnostically when a patient's clinical picture is unclear
- You use an occipital nerve block to confirm the clinical impression of the presence of occipital neuralgia
- You use the suprascapular nerve block to confirm a diagnosis of suspected entrapment of a nerve
- A patient's trigeminal nerve is blocked centrally at the trigeminal ganglion, along 1 of the 3 divisions, or at 1 of the many peripheral terminal branches
- A patient's nerve block is for preemptive analgesia

## Transcutaneous Electrical Nerve Stimulation (TENS)

TENS is the attachment of a transcutaneous nerve stimulator to the surface of the skin over the peripheral nerve to be stimulated. We cover TENS:

- When you use the device to determine the potential therapeutic usefulness of an electrical nerve stimulator
- For the treatment of patients with chronic, intractable pain (other than chronic low back pain), or acute post-operative pain

TENS device 30-day initial coverage trial can have 1 of these outcomes:

- Significantly relieves patient pain, so we'll consider it as a primary treatment
- Doesn't provide the patient significant pain relief, so you may consider PENS to see if an implanted peripheral nerve stimulator would provide sufficient pain relief

Unlike electronic cell-signaling treatment, TENS is an accepted way of assessing a patient's suitability for ongoing treatment with a transcutaneous (like a TENS machine) or an implanted nerve stimulator (like PENS, discussed on the next page).



## Percutaneous Electrical Nerve Stimulation (PENS)

PENS involves stimulation of peripheral nerves using a needle electrode inserted through the skin.

Similar to TENS, PENS device 30-day initial coverage trial can have 1 of these outcomes:

- Significantly relieves patient pain, so implanting electrodes is warranted and coverage will continue
- Doesn't provide the patient significant pain relief, so coverage will stop

Unlike electronic cell-signaling treatment, PENS is an accepted way of assessing a patient's suitability for ongoing treatment with an implanted nerve stimulator.

## Resources

- [Local Coverage Article: Standard Documentation Requirements for All Claims Submitted to DME MACs \(A55426\)](#)
- [Local Coverage Article: Transcutaneous Electrical Nerve Stimulators \(TENS\) - Policy Article \(A52520\)](#)
- [Local Coverage Determination: Nerve Blockade for Treatment of Chronic Pain and Neuropathy \(L35456\)](#)
- [Local Coverage Determination: Nerve Blockade for Treatment of Chronic Pain and Neuropathy \(L35457\)](#)
- [Local Coverage Determination: Peripheral Nerve Blocks \(L33933\)](#)
- [Local Coverage Determination: Peripheral Nerve Blocks \(L36850\)](#)
- [Local Coverage Determination: Transcutaneous Electrical Nerve Stimulators \(TENS\) \(L33802\)](#)
- [Medicare Carriers Manual](#), Part 3, Section 2049 (Definition of Drug or Biologicals)
- [Medicare NCD Manual](#): Chapter 1, Part 2, Section 160.7.1 (Assessing Patients Suitability for Electrical Nerve Stimulation Therapy)
- [Medicare Provider Compliance Tips: TENS](#)
- [National Coverage Determination: Vitamin B12 Injections to Strengthen Tendons, Ligaments, etc., of the Foot \(150.6\)](#)

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