# Peripheral Nerve Stimulators

Humana®
And Subsidiaries

**Original Effective Date:** 01/01/2024
**Effective Date:** 05/01/2025
**Review Date:** 04/08/2025
**Policy Number:** HUM-1140-005
**Line of Business:** Medicare

## Medicare Advantage Medical Coverage Policy

### Table of Contents





## Related Medicare Advantage Medical/Pharmacy Coverage Policies

Headache and Occipital Neuralgia Treatments

## Related CMS Documents

**Please refer to CMS Medicare Coverage Database for the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA). Refer to CMS website for the most current applicable CMS Online Manual System (IOMs) and Transmittals.**

**Humana and subsidiaries apply a Medicare Administrative Contractor's (MAC's) LCD to all requests (both Part A and Part B services) within the MAC's applicable geographic jurisdiction.**

| Type | Title | Document ID Number | Jurisdiction Medicare Administrative | Applicable States/Territories |
|---|---|---|---|---|

| | | | Contractors (MACs) | |
|---|---|---|---|---|
| NCD | Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy | 160.7.1 | | |
| NCD | Electrical Nerve Stimulators | 160.7 | | |
| NCD | Supplies Used in the Delivery of Transcutaneous Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation (NMES) | 160.13 | | |
| NCD | Transcutaneous Electrical Nerve Stimulation (TENS) for Acute Post-Operative Pain | 10.2 | | |
| NCD | Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP) | 160.27 | | |
| LCD<br>LCA | External Upper Limb Tremor Stimulator Therapy<br><br>Transcutaneous Electrical Joint Stimulation Devices<br><br>Transcutaneous Electrical Nerve Stimulators (TENS) | L39591<br>A59680<br><br>L34821<br>A52713<br><br>L33802<br>A52520 | DME A - Noridian Healthcare Solutions, LLC (DME MAC)<br><br>DME B - CGS Administrators, LLC (DME MAC)<br><br>DME C - CGS Administrators, LLC (DME MAC)<br><br>DME D - Noridian Healthcare Solutions, LLC (DME MAC) | CT, DC, DE, MA, MD, ME, NH, NJ, NY, PA, RI, VT<br><br>IL, IN, KY, MI, MN, OH, WI<br><br>AL, AR, CO, FL, GA, LA, MS, NC, NM, OK, SC, TN, TX, VA, WV, PR, US VI<br><br>AK, AZ, CA, HI, IA, ID, KS, MO, MT, ND, NE, NV, OR, SD, UT, WA, WY, American Samoa, Guam, Northern Mariana Islands |
| LCD<br>LCA | Peripheral Nerve Stimulation | L34328<br>A55530 | JE - Noridian Healthcare Solutions, LLC | CA, HI, NV, American Samoa, Guam, Northern Mariana Islands |
| LCD<br>LCA | Peripheral Nerve Stimulation | L37360<br>A55531 | JF - Noridian Healthcare Solutions, LLC | AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY |

| | | | | |
|---|---|---|---|---|
| LCD<br>LCA | Auricular Peripheral Nerve Stimulation (Electro-Acupuncture Device) | A55240 | JH - Novitas Solutions, Inc. (Part A/B MAC)<br><br>JL - Novitas Solutions, Inc. (Part A/B MAC) | AR, CO, LA, MS, NM, OK, TX<br><br>DE, DC, MD, NJ, PA |

## Description

Stimulation of the peripheral nerves has been proposed as a method to treat a wide array of conditions, including pain, nausea and vomiting or even recently has been proposed for essential tremors and restless legs syndrome. The devices may be referred to as peripheral nerve stimulators, electrical stimulators, or electrical stimulation; they may use electrodes on the skin or may be implanted beneath the skin. The term electrical stimulator is often used to reference transcutaneous electrical nerve stimulation (TENS); however, an electrical stimulator may be one of many different types of devices and therefore the terms are not interchangeable.

**Auricular electrostimulation** (also referred to as **auricular electroacupuncture** or **pulsed stimulation**) is the application of electrical impulses/stimulation to acupuncture points on the ear, generally using disposable, preprogrammed units which are worn behind the ear. It is theorized that stimulation of the corresponding acupuncture points will relieve pain in various locations in the body.

**Cala Transcutaneous Afferent Patterned Stimulation Therapy (Cala TAPS)** (also known as Cala kIQ; formerly known as Cala ONE or Cala Trio) was granted US Food & Drug Administration (FDA) clearance for treatment of hand tremors in adults with essential tremor (ET). The device is worn on the wrist and appears similar to a smart watch; it delivers an electrical stimulation to the median and radial nerves in the wrist. The electrical stimulation is purported to be relayed through the nervous system to the brain where it theoretically disrupts the neural network, temporarily reducing the tremors. The stimulation is self-administered, with the user being instructed to use it 40 minutes before a task with which the tremors interfere.

**Combined therapy**, which consists of **high frequency electrical stimulation and peripheral nerve block** (also referred to as **combination electrochemical therapy, combination electrochemical treatment** or **CET**), is purported to treat peripheral neuropathy by first injecting the peripheral nerve with a local anesthetic, followed by a high frequency electrical stimulation.

**Electroceutical therapy** utilizes a noninvasive device with a variety of electrical modalities as a proposed treatment for acute and chronic pain. The device is similar to TENS, except electroceutical treatments use higher electrical frequencies, altering the electric current to theoretically mimic the human bioelectric system. This therapy may also be referred to as **bioelectric nerve block**, **noninvasive neuron blockade**, **electroceutical neuron blockade** and **bioelectric treatment system**. An example of this is the **Hako-Med Pro ElecDT 2000**.

**H-Wave stimulation** is a form of electrical stimulation that differs from other types in terms of its waveform. The H-wave produces low frequency muscle stimulation and high frequency pain control. H-wave stimulation has been proposed for use in pain control for conditions such as complex regional pain syndrome (also known as CRPS or reflex sympathetic dystrophy), muscle sprains, temporomandibular joint dysfunctions or treatment of diabetic neuropathy.

**High frequency impulse therapy (HFIT)** purportedly mimics a frequency wave similar to that of implanted neuromodulation devices (ie, some spinal cord stimulators). The stimulation is delivered via electrodes, applied to the skin, which are directly attached to the stimulator (without the need for lead wires). An example of this device includes, but may not be limited to, the **ENSO** device.

**Interferential current stimulation (ICS)**, which may also be referred to as interferential therapy, is similar to TENS, in that both send electrical impulses from a portable, battery powered pulse generator to skin electrodes placed over the affected tissue. ICS differs from TENS, however, by allowing the electrical impulses to have a deeper penetration of the tissue. The **neo-GEN Series system** is a form of ICS; it uses an ultra-high frequency generator to produce pulsed electrical cell-signaling treatment (referred to as EcST). The neo-GEN Series system is not for home use.

**Microcurrent electrical nerve stimulation (MENS)** devices are noninvasive and apply precise, tightly controlled electrical current to specific areas on the body that correspond with classical acupuncture points. MENS is also referred to as **microelectrical therapy (MET)** or **microelectrical neurostimulation**. Examples of this type of device include, but may not be limited to, **Alpha-Stim M**, **Electro-Myopulse 75L**, **iReliev Microcurrent Pain Relief System** and **Myopulse**. The **ClearUP Sinus Pain Relief** device is FDA approved for relief of sinus pain due to allergic rhinitis, the flu or the common cold. It is purported to accomplish this by stimulation of the trigeminal nerve branches. It is available over-the-counter without a prescription.

The **Nidra NTX100 Tonic Motor Activation (TOMAC) System** has been proposed as a noninvasive neurostimulation treatment for symptoms of restless leg syndrome. Stimulation is delivered to the peroneal nerves via two bands worn around each leg overnight, which activates muscles to theoretically help reduce symptoms and improve sleep quality.

**Percutaneous electrical nerve field stimulation (PENFS)**, a variation of auricular electrostimulation, has been proposed as a treatment for functional abdominal pain associated with irritable bowel syndrome (IBS) in children 11 - 18 years of age. An example of a PENFS device is the **IB-Stim** stimulator. This device is a single-use, disposable battery-powered stimulator which is placed behind the ear. Low frequency electric pulses are delivered via electrodes to nerve branches of cranial nerves V, VII, IX and X as well as the occipital nerves.

Another proposed use for PENFS is the treatment of pain associated with opioid withdrawal. The **Bridge** medical device uses needle array electrodes rather than acupuncture needles that are placed on the ear/earlobe and connect to a pulse generator that has been attached behind the ear. As with the IB-Stim device, low frequency electric pulses are delivered via the electrodes to the nerve branches of cranial nerves V, VII, IX and X as well as the occipital nerves. The system, including the electrodes, is left in place for up to 5 days, at which time it is removed and discarded. Additional examples of similarly designed PENFS

devices (for the treatment of pain associated with opioid withdrawal) include the **Drug Relief V1** device and the **Morph Device**.

Other devices in this classification include the **NeuroSolutions 100 (NS100)** system and the **Primary Relief** system. Both use auricular stimulation points for location of the electrodes. The NS100 system has been FDA approved for treatment up to 56 days for chronic intractable pain due to diabetic peripheral neuropathy. The Primary Relief system was initially FDA approved for post-cesarean section pain; it has been granted an expanded approval for treatment of pain after cardiac surgery. It may be used for up to 3 days for either indication.

The **Sparrow Therapy System** is a variation of the PENFS devices. Rather than percutaneous needle array electrodes to deliver the stimulation, it utilizes transcutaneous electrodes attached to an earpiece to stimulate those same cranial and/or occipital nerves for treatment of opioid withdrawal. It is referred to as **transcutaneous auricular neurostimulation (tAN)** or a **transcutaneous nerve field stimulator**.

**Percutaneous electrical nerve stimulation (PENS)** uses very fine, acupuncture-like needles inserted into the tissues surrounding the spine. Electrical current (the same type as used in transcutaneous electrical nerve stimulation [TENS]) is applied to the needles which then stimulate the peripheral nerves. This treatment is performed by a healthcare professional in the office setting and is not intended for home use.

**Percutaneous neuromodulation therapy (PNT)** is a variation of PENS, but utilizes different electrical impulses than PENS. The electrical stimulation, which is an alternating low and high frequency current at varying pulse impulses, is delivered via needle-like electrodes which is purported to allow the stimulation to reach the deep tissue. An example of this type of device includes, but may not be limited to, the **BioWavePRO Neuromodulation Pain Therapy System**. This device is not for home use and requires administration by a healthcare provider, such as a physician or physical therapist, in a clinic or office setting. The **BioWaveGo** (a wearable version of PNT) and the **BioWaveHome** are available for home use and utilize the same type of electrical stimulation as the office version.

**Peripherally implanted nerve stimulation**, also referred to as **peripheral nerve stimulation (PNS)**, transmits an electrical current via an electrode that has been implanted adjacent or parallel to the selected peripheral nerve. This electrical current purportedly blocks or disrupts the normal transmission of pain signals. The electrodes are connected by a wire to the peripherally implanted neurostimulator (also known as an implantable subcutaneous target stimulator). An external generator (similar to a remote control device) controls the degree of stimulation the individual receives. Examples of peripherally implanted nerve stimulators include, but may not be limited to, the **Freedom Peripheral Nerve Stimulator** (previously the **StimQ system**), **MiniStim PNS**, **Nalu Neurostimulation system** and **Neuspera Nuity Neurostimulation System (NNS)**. The **Sprint PNS system** is a variation of PNS. It is a temporary peripheral nerve stimulation system which is implanted for up to 60 days.

A similar treatment is **peripheral nerve field stimulation (PNFS)**, which may also be referred to as **peripheral subcutaneous field stimulation (PSFS)**. In this particular treatment, the electrode leads are placed subcutaneously in the region of the pain; there the electrodes stimulate smaller peripheral nerves and nerve endings, theoretically allowing overlapping fields of multiple nerves to be stimulated.

A **permanent peripheral implantable neuromodulator** differs from PSFS/PNFS in that it targets a specific nerve, and not a general area/nerve field distribution. This minimally invasive procedure is proposed as another treatment option for an individual with chronic pain of peripheral pain origin. An example of this device includes, but may not be limited to, the **StimRouter system**. The **Altius Direct Electrical Nerve Stimulation System** utilizes a high-frequency alternating current (HFAC), and is proposed as a treatment option for an individual with chronic intractable phantom and residual lower limb post amputation pain in adult amputees. A cuff electrode is implanted on the targeted nerve near the amputation site, and connected via lead wires to the implanted pulse generator.

The **ReActiv8 implantable device** is a variation of an implantable neurostimulator that has been proposed for treatment of low back pain. Rather than disrupting transmission of pain signals, it purports that by stimulating the nerves that innervate the weakened lumbar multifidus muscle, neuromuscular control will be re-established, which over time may improve functional lumbar spine stability and decrease back pain. Treatment with the ReActiv8 may also be referred to as restorative neurostimulation.

**Pulsed electrical stimulation (PES)** (also referred to as **electrical joint stimulation**) is a noninvasive, low amplitude device designed to decrease pain and increase function in an individual with conditions such as osteoarthritis (OA) of the knee, carpal tunnel syndrome, rheumatoid arthritis (RA) of the hand or diabetic complications such as foot ulcers or diabetic neuropathy. The device consists of a signal generator, signal applicator and contact elements encased in a soft wrap with a Velcro closure, which is wrapped around the affected body part. Examples of this type of device include, but may not be limited to, the **BioniCare Hand System** (for OA or RA of the hand), the **BioniCare Knee System** (which includes the **OActive Knee Brace**) used for OA of the knee (integrates both the pulsed joint stimulator with their specialized knee brace to theoretically provide both stimulation and support of the knee joint) and the **J-Stim 1000** which is proposed for use in OA of the knee or for rheumatoid arthritis of the hand. **High-volt pulsed galvanic (HVPG or HGV) stimulation** is another type of pulsed electrical stimulator that is similar to BioniCare; however, HVPG is proposed for the treatment of carpel tunnel syndrome and/or complications from diabetes, such as foot ulcers or diabetic neuropathy.

**Scrambler therapy/Calmare pain therapy treatment** (also known as **transcutaneous electrical modulation pain reprocessing** or **TEMPR**) is intended to interrupt transmission of pain signals by delivering electrical stimulation that is interpreted by the nervous system as no pain (the stimulation scrambles the pain signal). Cutaneous nerves are stimulated using 5 surface electrode pairs that are placed in the dermatomes above and below the pain area. Unlike conventional TENS, scrambler therapy is administered in the office setting under physician supervision.

**Sympathetic therapy** is a type of noninvasive therapy suggested for the treatment of chronic pain that uses electrostimulation of the peripheral nerves designed to stimulate the sympathetic nervous system. Unlike TENS, sympathetic therapy does not treat local pain but is designed to induce a systemic effect via the sympathetic nervous system.

**Transcutaneous electrical acupoint stimulation**, also known as **acustimulation**, has been proposed as a method of treating severe nausea and vomiting that does not respond to other conservative treatments. A watch-like device is placed on the wrist and provides very mild electrical impulses to stimulate the median

nerve (which is an acupuncture point thought to be effective for the treatment of nausea and vomiting). An example of a device used for this treatment includes, but may not be limited to, the **ReliefBand**.

A variation of transcutaneous electrical acupoint stimulation is **transdermal neuromodulation**. It is proposed as treatment for chemotherapy-induced nausea and vomiting. It purportedly works by stimulating the median nerve on the underside of the wrist.

**Transcutaneous magnetic stimulation**, also referred to as **therapeutic magnetic resonance (TMR)**, is a type of stimulation that is purported as treatment for chronic pain. TMR delivers a focused low-frequency pulsed electromagnetic energy via two surgical steel probes that are placed against the surface of the skin, without piercing it. This treatment must be performed by a healthcare professional in an office or clinic setting. **Axon Therapy** is an FDA-approved noninvasive treatment for neuropathic pain that is similar to TMR; it delivers focused magnetic pulses via a figure-8-shaped coil placed on the area of the body with nerve damage. This treatment must also be performed by a healthcare professional in an office or clinic setting.

A variation of TMR is **pulsed electromagnetic field therapy (PEMF)**; unlike TMR, this may be used at home, and utilizes a wrap that contains the coils that provide the electromagnetic energy. An example of a device used for the delivery of PEMF is the **OrthoCor Active System**; there are two forms of this device – one is for use on the joints (ie, ankle, elbow, knee, shoulder and wrist) and the other for the back and neck. **Targeted pulsed electromagnetic field therapy (tPEMF)** is similar to PEMF and has been proposed as a treatment option for postoperative pain and swelling. An example of this device includes, but may not be limited to, the **SofPulse tPEMF device**. As with the OrthoCor, it is a wearable device, and can be placed directly over bandages, casts or clothing.

**Transcutaneous electrical nerve stimulation (TENS)** is the most common form of electrical stimulation used for pain management therapy. TENS sends electrical impulses from a portable, battery powered pulse generator using skin electrodes placed over the affected tissue or nerve(s).

A number of electrical stimulators (the majority are TENS units) are available for purchase over-the-counter (OTC) (off-the-shelf) without a physician prescription. Examples of these devices include, but may not be limited to, the **ActiPatch, Aleve Direct Therapy TENS, Avazzia, Icy Hot Smart Relief TENS, Viverity Pain Relief Pad - Rechargeable TENS** and **WiTouch Pro Bluetooth Wireless TENS Device**.

The **Quell** device is another example of a TENS unit that is available OTC; it is also the first and only OTC electrical stimulator to receive FDA approval for use during sleep. This device consists of a band worn around the upper calf to theoretically provide systemic relief of chronic pain and is controlled by an individual's smartphone or tablet. It has been granted an additional expanded indication for moderate to severe symptoms of chemotherapy-induced peripheral neuropathy that have persisted for at least 6 months following discontinuation of chemotherapy.

**Transcutaneous pulsed radiofrequency stimulation** is another proposed treatment for chronic intractable pain and/or as an adjunctive treatment in the management of postsurgical pain, post-traumatic acute pain, as well as an adjunct for pain control due to rehabilitation. This treatment must be performed by a healthcare professional in an office or clinic setting. An example of a device used in this treatment includes, but may not be limited to, the **STIMPOD NMS460**.

## Coverage Determination

*Humana and subsidiaries follow the Medicare requirements that only allow coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.*

*Humana and subsidiaries apply any applicable National Coverage Determination (NCD) and any applicable Local Coverage Determinations (LCDs) to the services and jurisdiction at issue. See the Related CMS Documents Section above for any such NCDs or LCDs.*

Please refer to the above CMS guidance for **external upper limb tremor stimulation, transcutaneous electrical nerve stimulators (TENS)** and **TENS supplies**.

**Peripheral Nerve Stimulation (PNS)**
While NCD 160.7 states that "[p]ayment may be made under the prosthetic device benefit for implantable peripheral nerve stimulators," it does not provide additional guidance as to when the use of a peripheral nerve stimulator should be considered reasonable and necessary.

For jurisdictions without an LCD, Humana and subsidiaries determine medical necessity for **peripheral nerve stimulation** based on the criteria contained in LCD - Peripheral Nerve Stimulation (L37360).

Devices used for peripheral nerve stimulation must have FDA approval to be used as such.

*The use of the criteria above provides clinical benefits highly likely to outweigh any clinical harms (eg, adverse effects including, but not limited to, lead migration, lead fracture, battery failure, pain related to device components, hematoma, hemorrhage, wound dehiscence and infection, skin erosion and neurological injury[8]). Services that do not meet the criteria above are not medically reasonable and necessary and may result in unnecessary exposure to potential complications. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.*

## Coverage Limitations

US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage

**Peripheral Nerve Stimulation**
For jurisdictions without an LCD, Humana and subsidiaries determine medical necessity for **peripheral nerve stimulators or stimulation therapy** for the treatment of pain and associated conditions based on the criteria contained in LCD - Peripheral Nerve Stimulation (L37360).

**Auricular Peripheral Nerve Stimulation (Electro-Acupuncture Device)**
For jurisdictions without an LCD, Humana and subsidiaries determine medical necessity for **auricular peripheral nerve stimulation** for any indication (including to aid in reduction of opioid withdrawal symptoms) based on the guidance contained in LCA - Billing and Coding: Auricular Peripheral Nerve Stimulation (Electro-Acupuncture Device) (A55240).

**Peripheral Nerve Field Stimulation (PNFS)**
For jurisdictions without an LCD, Humana and subsidiaries determines medical necessity for **peripheral nerve field stimulation (PNFS)** (also referred to as peripheral subcutaneous field stimulation [PSFS]) for any condition based on the criteria contained in LCD - Peripheral Nerve Stimulation (L37360).

**Transcutaneous Electrical Joint Stimulation Devices**
Humana and subsidiaries determine medical necessity for **transcutaneous electrical joint stimulation devices** (also referred to as pulsed electrical stimulation [PES]) for the treatment of osteoarthritis or any other condition based on the criteria contained in LCD - Transcutaneous Electrical Joint Stimulation Devices (TEJSD) (L34821).

**Miscellaneous Electrical Nerve Stimulators/Stimulation Therapy**
The following **electrical stimulators or stimulation therapy** for the treatment of pain/associated conditions and nausea/vomiting will **not** be considered medically reasonable and necessary:

- Combined therapy high frequency electrical stimulation and peripheral nerve block (also referred to as combination electrochemical therapy, combination electrochemical treatment or CET); **OR**
- Electroceutical therapy (also known as bioelectric nerve block); **OR**
- High frequency impulse therapy (HFIT); **OR**
- High-volt galvanic stimulation (HVPG or HVG); **OR**
- Percutaneous neuromodulation therapy; **OR**
- Sympathetic therapy; **OR**
- Transcutaneous magnetic stimulation (also known as therapeutic magnetic resonance [TMR]); **OR**
- Transcutaneous pulsed radiofrequency stimulation; **OR**
- Transdermal neuromodulation

A review of the current medical literature shows that there is **no evidence** to determine that these services are standard medical treatments. There is an absence of current, widely-used treatment guidelines or

acceptable clinical literature (as defined by CMS) examining benefit and long-term clinical outcomes establishing the value of these services in clinical management.

The following **electrical stimulators or stimulation therapy** for the treatment of pain and associated conditions will **not** be considered medically reasonable and necessary:

- H-wave stimulation; **OR**
- Interferential current stimulation (ICS) (interferential therapy); **OR**
- Microcurrent electrical nerve stimulation (MENS); **OR**
- Percutaneous electrical nerve field stimulation (PENFS) of the cranial nerves (without implantation); **OR**
- Pulsed electromagnetic field therapy (PEMF); **OR**
- Scrambler therapy/Calmare pain therapy treatment (also known as transcutaneous electrical modulation pain reprocessing or TEMPR); **OR**
- Targeted pulsed electromagnetic therapy (tPEMF); **OR**
- Transcutaneous auricular neurostimulation (tAN) (also known as transcutaneous nerve field stimulator)

A review of the current medical literature shows that the **evidence is insufficient** to determine that these services are standard medical treatment. There is an absence of current, widely-used treatment guidelines or acceptable clinical literature (as defined by CMS) examining benefit and long-term clinical outcomes establishing the value of these services in clinical management.

**External lower extremity nerve stimulation to the peroneal nerve(s)** for the **treatment restless leg syndrome (RLS)** will **not** be considered medically reasonable and necessary. A review of the current medical literature shows that the **evidence is insufficient** to determine that this service is standard medical treatment. There is an absence of current, widely-used treatment guidelines or acceptable clinical literature (as defined by CMS) examining benefit and long-term clinical outcomes establishing the value of this service in clinical management.

**Transcutaneous electrical acupoint stimulation** for the **treatment of nausea and vomiting** will **not** be considered medically reasonable and necessary. A review of the current medical literature shows that the **evidence is insufficient** to determine that this service is standard medical treatment. There is an absence of current, widely-used treatment guidelines or acceptable clinical literature (as defined by CMS) examining benefit and long-term clinical outcomes establishing the value of this service in clinical management.

## Summary of Evidence

***External Lower Extremity Stimulation for Treatment of RLS***
Stimulation of the peroneal nerves has been proposed as a treatment for symptoms associated with RLS. One randomized controlled trial, one randomized crossover study and one case series were identified by an independent technology assessment organization[28] in a report for the Nidra Tonic Motor Activation (TOMAC) system. All were of small sample sizes (N=20-133) and short follow up (1 year or less). Additional larger trials with longer term follow up are needed to determine efficacy and safety.

***H-Wave Stimulation***
An independent technology assessment organization[35] reports findings of two randomized-controlled trials (RCTs) using H-wave stimulation for treatment of pain related to peripheral diabetic neuropathy. Both studies were relatively small, with a total of 32 patients being treated with H-wave therapy and 23 given sham therapy. The organization determined that no conclusions could be drawn, as the evidence was insufficient in terms of quantity, quality and size of effect. The authors also note that there were not any studies to compare the effectiveness of H-wave therapy to other treatments. Additional trials that enroll larger numbers of patients, use more rigorous methods and report more outcomes (including validated scales for function and quality of life) may help clarify the efficacy of an H-wave device and a sham device.

***Interferential Current Stimulation (ICS)***
An independent technology assessment organization[67] found little evidence from available randomized controlled trials that ICS is effective in relieving pain associated with soft tissue injury. The authors report that two of the studies failed to document any beneficial effect of ICS beyond that which was also provided by placebo treatment. Many of the studies reviewed did not address any long-term efficacy, although short-term pain relief was noted. The authors concluded that there is significant need for further randomized, double-blind, placebo-controlled studies of the efficacy of ICS in the treatment of low back pain and other disorders in which pain results from inflammation or nerve, muscle or connective tissue damage/injury, as well as the need to establish treatment parameters of pulse rate, duration and amplitude of the interferential current.

***Microcurrent Electrical Nerve Stimulation (MENS)***
An independent technology assessment organization[62] concludes that there is insufficient evidence to assess the efficacy of MENS for the treatment of pain associated with lateral epicondylitis. Substantial uncertainty remains regarding whether MENS provides reduction in pain compared with standard care in individuals with lateral epicondylitis. There is insufficient evidence to assess the efficacy of MENS for the treatment of pain associated with lower back disorders, Achilles tendinopathy, TMJ disorders, or bruxism. This conclusion is due to the paucity of evidence evaluating MENS in any one indication.[64]

***Percutaneous Electrical Nerve Field Stimulation (PENFS)***
An independent technology assessment organization[52] found evidence from 1 fair-quality randomized sham-controlled trial with a subgroup analysis suggesting that the IB-Stim is associated with clinically significant benefits in pain and function at 3 to 4 weeks that were not sustained at 8 to 12 weeks. No systematic reviews were identified. The authors conclude that a review of the clinical studies suggests no/unclear support for the IB-Stim device. That same organization[50] provides a review of a similar device, the Bridge, reporting on a single study which suggests the device alleviates symptoms of opioid withdrawal;

however, the study does not have a control group and therefore does not inform how relief compares with sham devices or other pharmacologic or behavioral interventions. Further research is needed to fully understand the findings.

***Pulsed Electromagnetic Field Therapy (PEMF)***
AHRQ[2] identified one fair-quality trial, which found PEMF was associated with slight improvements in function and pain versus sham short-term, but the differences may not be clinically significant. The authors also noted that more individuals who received PEMF versus sham reported throbbing or warming sensation, or aggravation of pain, though the difference was not statistically significant.

An evidence-based clinical resource[84] notes that in a systematic review of low-energy pulsed electromagnetic therapy in patients with neck pain of variable duration, there is low-quality evidence of minimal benefit (limited to immediate post-treatment pain relief) among those with chronic neck pain or whiplash syndrome.

***Scrambler Therapy/Calmare Pain Therapy Treatment***
A meta-analysis was conducted by Jin, Kim, Hur, and Myung[73] regarding the efficacy of scrambler therapy for management of chronic pain. The authors identified 7 RCTs that met the inclusion criteria, and found that overall, scrambler therapy marginally decreased pain scores after the end of treatment compared with the control group. Limitations were noted to be small sample sizes for the trials, as well as low methodological quality. The authors concluded that though scrambler therapy seems to be effective in the management of individuals with chronic pain, further, large RCTs are needed to confirm their findings.

***Targeted Pulsed Electromagnetic Therapy (tPEMF)***
An independent technology assessment organization[39] found limited evidence from 3 very small RCTs on SofPulse use for postoperative pain management after breast surgery, suggesting it is safe and may relieve short-term pain and may reduce (but not eliminate) narcotic use compared to a sham device, though the authors went on to note that the studies assessed too few individuals to be conclusive, and results need to be confirmed in larger, longer-term RCTs examining different surgery types and comparing SofPulse to other pain control techniques. The organization concluded that the evidence is inconclusive due to too few data.

***Transcutaneous Auricular Neurostimulation (tAN)/Transcutaneous Nerve Field Stimulator***
Tirado et al[81] report on a prospective inpatient trial which included a randomized, sham-controlled, double-blind study of 31 individuals with opioid use disorder, in the management of opioid withdrawal syndrome (OWS) following abrupt opioid discontinuation, utilizing a tAN device. The study provided positive response to the treatment, finding it to be safe and well-tolerated with clinically meaningful sustained reductions in opioid withdrawal symptoms. The authors do acknowledge study limitations, including a relatively small sample size of test participants, as well as the duration of the double-blind period in which the treatment groups received the active tAN treatment versus the sham treatment. Future trials that aim to determine the effectiveness of tAN therapy would further benefit with a control group that extends the entire duration of the treatment phase.

***Transcutaneous Electrical Acupoint Stimulation***
An independent technology assessment organization[36] reported on a systematic review by Matthews et al, which concludes that there is a lack of high quality evidence to support any intervention for treatment of nausea and vomiting in early pregnancy, as well as reporting on a systematic review by Cheong et al, which assesses postoperative nausea and vomiting (PONV) interventions. The organization concluded that acupoint stimulation may be beneficial in prevention and treatment of PONV, and the evidence justifies future high-quality studies.

## Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

| CPT® Code(s) | | Comments |
|---|---|---|
| 64553 | Percutaneous implantation of neurostimulator electrode array; cranial nerve | |
| 64555 | Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve) | |
| 64575 | Open implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve) | |
| 64585 | Revision or removal of peripheral neurostimulator electrode array | |
| 64590 | Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling | |
| 64595 | Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver | |
| 64596 | Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator, including imaging guidance, when performed; initial electrode array | |
| 64597 | Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator, including imaging guidance, when performed; each additional electrode array (List separately in addition to code for primary procedure) | |
| 64598 | Revision or removal of neurostimulator electrode array, peripheral nerve, with integrated neurostimulator | |
| 64999 | Unlisted procedure, nervous system | |
| 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 | |
| **CPT® Category III Code(s)** | **Description** | **Comments** |
| 0278T | Transcutaneous electrical modulation pain reprocessing (eg, scrambler therapy), each treatment session (includes placement of electrodes) | |
| 0720T | Percutaneous electrical nerve field stimulation, cranial nerves, without implantation | |
| 0766T | Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, initial treatment, with identification and marking of the treatment location, including noninvasive electroneurographic localization (nerve conduction localization), when performed; first nerve | |
| 0767T | Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, initial treatment, with identification and marking of the treatment location, including noninvasive electroneurographic localization (nerve conduction localization), when performed; each additional nerve (List separately in addition to code for primary procedure) | |
| 0768T | Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, subsequent treatment, including noninvasive electroneurographic localization (nerve conduction localization), when performed; first nerve | |
| 0769T | Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, subsequent treatment, including noninvasive electroneurographic localization (nerve conduction localization), when performed; each additional nerve (List separately in addition to code for primary procedure) | |
| 0783T | Transcutaneous auricular neurostimulation, set-up, calibration, and patient education on use of equipment | |
| **HCPCS Code(s)** | **Description** | **Comments** |
| A4542 | Supplies and accessories for external upper limb tremor stimulator of the peripheral nerves of the wrist | |
| A4543 | Supplies for transcutaneous electrical nerve stimulator, for nerves in the auricular region, per month | **New Code Effective Date 10/01/2024** |

| | | |
|---|---|---|
| A4544 | Electrode for external lower extremity nerve stimulator for restless legs syndrome | **New Code Effective Date 10/01/2024** |
| 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 | |
| C1827 | Generator, neurostimulator (implantable), non-rechargeable, with implantable stimulation lead and external paired stimulation controller | |
| C9807 | Nerve stimulator, percutaneous, peripheral (e.g., sprint peripheral nerve stimulation system), including electrode and all disposable system components, nonopioid medical device (must be a qualifying Medicare nonopioid medical device for postsurgical pain relief in accordance with Section 4135 of the CAA, 2023 | **New Code Effective Date 01/01/2025** |
| E0720 | Transcutaneous electrical nerve stimulation (TENS) device, two-lead, localized stimulation | |
| E0721 | Transcutaneous electrical nerve stimulatory, stimulates nerves in the auricular region | **New Code Effective Date 10/01/2024** |
| 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) | |
| E0734 | External upper limb tremor stimulator of the peripheral nerves of the wrist | |
| E0743 | External lower extremity nerve stimulator for restless legs syndrome, each | **New Code Effective Date 10/01/2024** |
| E0762 | Transcutaneous electrical joint stimulation device system, includes all accessories | |
| E0765 | FDA approved nerve stimulator, with replaceable batteries, for treatment of nausea and vomiting | |
| G0283 | Electrical stimulation (unattended), to one or more areas for indication(s) other than wound care, as part of a therapy plan of care | |
| K1018 | External upper limb tremor stimulator of the peripheral nerves of the wrist | |
| K1019 | Monthly supplies for use of device coded at K1018 | |

| | | |
|---|---|---|
| L8678 | Electrical stimulator supplies (external) for use with implantable neurostimulator, per month | |
| L8679 | Implantable neurostimulator, pulse generator, any type | |
| L8680 | Implantable neurostimulator electrode, each | |
| L8685 | Implantable neurostimulator pulse generator, single array, rechargeable, includes extension | |

## References

1. Agency for Healthcare Research and Quality (AHRQ). Comparative Effectiveness Review. Interventional treatments for acute and chronic pain: systematic review. https://ahrq.gov. Published September 2021.

2. Agency for Healthcare Research and Quality (AHRQ). Comparative Effectiveness Review. Noninvasive nonpharmacological treatment for chronic pain: a systematic review. https://ahrq.gov. Published June 2018.

3. American Academy of Neurology (AAN). Assessment: efficacy of transcutaneous electric nerve stimulation in the treatment of pain in neurologic disorders (an evidence-based review). https://www.aan.com. Published January 12, 2010. Updated April 15, 2024.

4. American Academy of Neurology (AAN). Evidence based guideline update: treatment of essential tremor. https://www.aan.com. Published October 19, 2011. Updated July 16, 2022.

5. American Academy of Neurology (AAN). Practice guideline summary: treatment of restless legs syndrome in adults. https://www.aan.com. Published November 2016. Updated October 22, 2022.

6. American Academy of Orthopaedic Surgeons (AAOS). Evidence-Based Clinical Practice Guideline. Management of osteoarthritis of the knee (non-arthroplasty). 3rd edition. https://www.aaos.org. Published August 31, 2021.

7. American College of Physicians (ACP). Nonpharmacologic and pharmacologic management of acute pain from non-low back, musculoskeletal injuries in adults: a clinical guideline from the American College of Physicians and American Academy of Family Physicians. https://www.acponline.org. Published 2020.

8. American Society of Interventional Pain Physicians (ASIPP). Comprehensive evidence-based guidelines for implantable peripheral nerve stimulation (PNS) in the management of chronic pain: from the American Society Of Interventional Pain Physicians (ASIPP). https://asipp.org. Published 2024.

9. American Society of Pain and Neuroscience (ASPN). Evidence-based guidelines from the American Society of Pain and Neuroscience for the use of implantable peripheral nerve stimulation in the treatment of chronic pain. https://aspnpain.com. Published August 2022.

10. American Society of Pain and Neuroscience (ASPN). The American Society of Pain and Neuroscience (ASPN) evidence-based clinical guideline of interventional treatments for low back pain. https://aspnpain.com. Published December 2022.

11. Ardeshiri A, Amann M, Thomson S, Gilligan C. Application of restorative neurostimulation for chronic mechanical low back pain in an older population with 2-year follow up. *Reg Anesth Pain Med.* 2024;0:1-6.

12. Centers for Medicare & Medicaid Services (CMS). Local Coverage Article (LCA). Billing and coding: auricular peripheral nerve stimulation (electro-acupuncture device) (A55240). https://cms.gov. Published August 11, 2016. Updated January 1, 2023.

13. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). External upper limb tremor stimulator therapy (L39591). https://cms.gov. Published April 7, 2024.

14. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Peripheral nerve stimulation (L34328). https://cms.gov. Published October 1, 2015. Updated December 1, 2019.

15. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Peripheral nerve stimulation (L37360). https://cms.gov. Published August 27, 2028. Updated December 1, 2019.

16. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Transcutaneous electrical joint stimulation devices (TEJSD) (L34821). https://cms.gov. Published October 1, 2015. Updated January 1, 2020.

17. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Transcutaneous electrical nerve stimulators (TENS) (L33802). https://cms.gov. Published October 1, 2015. Updated January 1, 2024.

18. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD). Assessing patient's suitability for electrical nerve stimulation (160.7.1). https://cms.gov. Published June 19, 2006.

19. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD). Electrical nerve stimulators (160.7). https://cms.gov. Published August 7, 1995.

20. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD). Supplies used in the delivery of transcutaneous electrical nerve stimulation (TENS) and neuromuscular electrical stimulation (NMES) (160.13). https://cms.gov. Published July 14, 1988.

21. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD). Transcutaneous electrical nerve stimulation (TENS) for acute post-operative pain (10.2). https://cms.gov. Published June 8, 2012.

22. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD). Transcutaneous electrical nerve stimulators (TENS) for chronic low back pain (CLBP) (160.27). https://cms.gov. Published June 8, 2012.

23. ECRI Institute. Clinical Evidence Assessment. Cala Transcutaneous Afferent Patterned Stimulation Therapy (Cala Health, Inc.) for essential tremor. http://home.ecri.org. Published January 13, 2022. Updated February 13, 2024.

24. ECRI Institute. Clinical Evidence Assessment. Freedom Peripheral Nerve Stimulator (Curonix, Inx.) for treating chronic pain. http://home.ecri.org. Published March 7, 2024.

25. ECRI Institute. Clinical Evidence Assessment. IB-Stim (Innovative Health Solutions) for treating abdominal pain in patients with irritable bowel syndrome. http://home.ecri.org. Published February 10, 2021.

26. ECRI Institute. Clinical Evidence Assessment. Implantable peripheral nerve stimulation devices for treating chronic pain. http://home.ecri.org. Published February 16, 2012. Updated July 28, 2023.

27. ECRI Institute. Clinical Evidence Assessment. Nalu Neurostimulation System (Nalu Medical, Inc.) for treating chronic pain. http://home.ecri.org. Published February 22, 2024.

28. ECRI Institute. Clinical Evidence Assessment. Nidra Tonic Motor Activation System (Noctrix Health, Inc.) for treating restless legs syndrome. http://home.ecri.org. Published January 30, 2024.

29. ECRI Institute. Clinical Evidence Assessment. Percutaneous electrical nerve field stimulation for treating abdominal pain in children with irritable bowel syndrome. http://home.ecri.org. Published December 30, 2024.

30. ECRI Institute. Clinical Evidence Assessment. Quell Wearable Pain Relief Technology (Neuromatrix, Inc.) for treating fibromyalgia symptoms. http://home.ecri.org. Published August 16, 2022.

31. ECRI Institute. Clinical Evidence Assessment. ReActiv8 Implantable Neurostimulation System (Mainstay Medical Ltd.) for treating chronic low-back pain. http://home.ecri.org. Published June 17, 2021. Updated February 24, 2025.

32. ECRI Institute. Clinical Evidence Assessment. Sparrow Ascent (Spark Biomedical, Inc.) for treating opioid withdrawal syndrome. http://home.ecri.org. Published February 4, 2025.

33. ECRI Institute. Clinical Evidence Assessment. Sprint Peripheral Nerve Stimulation System (SPR Therapeutics, LLC) for treating pain. http://home.ecri.org. Published May 18, 2018. Updated December 1, 2023.

34. ECRI Institute. Clinical Evidence Assessment. StimRouter Neuromodulation System (Bioness, Inc.) for treating peripheral nerve pain. http://home.ecri.org. Published April 24, 2018. Updated May 11, 2020.

35. ECRI Institute. Evidence Report. H-wave device stimulation therapy for pain management. http://home.ecri.org. Published April 2, 2009.

36. ECRI Institute. Hotline Response. Acustimulation therapy for treating nausea and vomiting. http://home.ecri.org. Published June 17, 2014.

37. ECRI Institute. Hotline Response. Implantable peripheral nerve stimulation devices for trigeminal neuralgia. http://home.ecri.org. Published June 10, 2016.

38. ECRI Institute. Hotline Response. Pulsed electromagnetic field therapy for musculoskeletal pain. http://home.ecri.org. Published July 8, 2015.

39. ECRI Institute. Product Brief. SofPulse Targeted Pulsed Electromagnetic Therapy (Endonovo Therapeutics, Inc.) for managing postoperative pain. http://home.ecri.org. Published December 3, 2019.

40. Hayes, Inc. Clinical Research Response. StimRouter (Bioventus) for the treatment of chronic pain. https://evidence.hayesinc.com. Published September 21, 2023.

41. Hayes, Inc. Emerging Technology Report. Quell wearable neurostimulation device for fibromyalgia. https://evidence.hayesinc.com. Published June 2, 2022.

42. Hayes, Inc. Evidence Analysis Research Brief. Alpha-Stim (Electromedical Products International, Inc.) for treatment of chronic pain. https://evidence.hayesinc.com. Published March 30, 2023.

43. Hayes, Inc. Evidence Analysis Research Brief. Nalu Neurostimulation System (Nalu Medical Inc.) for treatment of chronic pain of peripheral nerve origin. https://evidence.hayesinc.com. Published October 16, 2023.

44. Hayes, Inc. Evidence Analysis Research Brief. Percutaneous electrical nerve stimulation for treatment of low back pain. https://evidence.hayesinc.com. Published December 22, 2022.

45. Hayes, Inc. Evidence Analysis Research Brief. Peripheral nerve stimulation for the treatment of superior cluneal neuralgia. https://evidence.hayesinc.com. Published May 2, 2024.

46. Hayes, Inc. Evidence Analysis Research Brief. Peripheral nerve stimulation for treatment of shoulder subluxation poststroke. https://evidence.hayesinc.com. Published September 14, 2023.

47. Hayes, Inc. Evidence Analysis Research Brief. Sparrow Ascent (Spark Biomedical) for management of opioid withdrawal symptoms. https://evidence.hayesinc.com. Published March 13, 2024.

48. Hayes, Inc. Evidence Analysis Research Brief. Transcutaneous electrical nerve stimulation for knee osteoarthritis. https://evidence.hayesinc.com. Published July 13, 2023.

49. Hayes, Inc. Evolving Evidence Review. Axon Therapy (Neuralace Medical Inc.) for chronic nerve pain. https://evidence.hayesinc.com. Published August 1, 2022. Updated August 29, 2024.

50. Hayes, Inc. Evolving Evidence Review. Bridge Device (formerly NSS-2) (Masimo) for opioid withdrawal. https://evidence.hayesinc.com. Published August 11, 2021. Updated August 29, 2024.

51. Hayes, Inc. Evolving Evidence Review. Cala Trio (Cala Health, Inc.) for treatment of essential tremor. https://evidence.hayesinc.com. Published January 5, 2022. Updated January 19, 2024.

52. Hayes, Inc. Evolving Evidence Review. IB-Stim (NeurAxis) for treatment of pain associated with irritable bowel syndrome in adolescents. https://evidence.hayesinc.com. Published July 14, 2022. Updated July 17, 2024.

53. Hayes, Inc. Evolving Evidence Review. neoGEN-Series System (RST-Sanexas) for treatment of neuropathic pain. https://evidence.hayesinc.com. Published January 5, 2023. Updated February 6, 2025.

54. Hayes, Inc. Evolving Evidence Review. ReActiv8 Implantable Neurostimulation System (Mainstay Medical Ltd.) for chronic low back pain. https://evidence.hayesinc.com. Published January 31, 2025.

55. Hayes, Inc. Evolving Evidence Review. SPRINT PNS System (SPR Therapeutics) for chronic pain. https://evidence.hayesinc.com. Published February 27, 2025.

56. Hayes, Inc. Health Technology Assessment. Percutaneous peripheral nerve stimulation for treatment of chronic pain. https://evidence.hayesinc.com. Published May 5, 2022. Updated May 8, 2024.

57. Hayes, Inc. Health Technology Assessment. Peripheral nerve field stimulation for treatment of chronic low back pain. https://evidence.hayesinc.com. Published April 22, 2021. Updated April 17, 2024.

58. Hayes, Inc. Health Technology Assessment. Scrambler/Calmare Pain Therapy (Calmare Therapeutics Inc.) for the management of chronic pain related to cancer or cancer treatment. https://evidence.hayesinc.com. Published March 30, 2020. Updated April 25, 2023.

59. Hayes, Inc. Health Technology Assessment. Scrambler/Calmare Pain Therapy (Calmare Therapeutics Inc.) for the management of pain not related to cancer. https://evidence.hayesinc.com. Published April 6, 2020. Updated June 9, 2023.

60. Hayes, Inc. Health Technology Assessment. Transcutaneous electrical nerve stimulation for chronic low back pain. https://evidence.hayesinc.com. Published March 27, 2024.

61. Hayes, Inc. Health Technology Brief. BioniCare Knee System (VQ OrthoCare) for treatment of osteoarthritis of the knee. https://evidence.hayesinc.com. Published October 17, 2011. Updated October 18, 2013.

62. Hayes, Inc. Health Technology Brief. Microcurrent electrical therapy for the treatment of musculoskeletal pain. https://evidence.hayesinc.com. Published October 26, 2018. Updated January 21, 2021.

63. Hayes, Inc. Health Technology Brief. Microcurrent electrical therapy for the treatment of postoperative pain. https://evidence.hayesinc.com. Published November 1, 2018. Updated January 21, 2021.

64. Hayes, Inc. Health Technology Brief. P-Stim (Biegler GmbH) auricular electroacupuncture for pain management. https://evidence.hayesinc.com. Published December 31, 2012. Updated December 10, 2014.

65. Hayes, Inc. Health Technology Brief. Percutaneous electrical nerve stimulation for treatment of low back pain. https://evidence.hayesinc.com. Published February 9, 2017. Updated January 10, 2019.

66. Hayes, Inc. Health Technology Brief. Pulsed electromagnetic field (PEMF) therapy for treatment of postoperative knee pain and edema. https://evidence.hayesinc.com. Published September 24, 2015. Updated July 25, 2017.

67. Hayes, Inc. Medical Technology Directory. Interferential therapy for pain and bone fractures. https://evidence.hayesinc.com. Published April 28, 2008. Updated April 2, 2012.

68. Hayes, Inc. Medical Technology Directory. Transcutaneous electrical nerve stimulation for acute pain. https://evidence.hayesinc.com. Published July 23, 2010. Updated June 3, 2014.

69. Hayes, Inc. Medical Technology Directory. Transcutaneous electrical nerve stimulation for knee osteoarthritis. https://evidence.hayesinc.com. Published January 30, 2019. Updated January 19, 2022.

70. Hayes, Inc. Medical Technology Directory. Transcutaneous electrical nerve stimulation for postoperative and procedural pain. https://evidence.hayesinc.com. Published April 30, 2010. Updated April 2, 2014.

71. Hayes, Inc. Medical Technology Directory. Transcutaneous electrical nerve stimulation (TENS) for the treatment of nausea and vomiting. https://evidence.hayesinc.com. Published February 5, 2006. Updated March 17, 2010.

72. International Society for the Advancement of Spine Surgery (ISASS). International Society for the Advancement of Spine Surgery statement: restorative neurostimulation for chronic mechanical low back pain resulting from neuromuscular instability. https://www.ijssurgery.com. Published 2023.

73. Jin Y, Kim D, Hur J, Myung S-K. Efficacy of scrambler therapy for management of chronic pain: a meta-analysis of randomized controlled trials. *Pain Physician*. 2022;25:E931-E939.

74. North American Spine Society (NASS). Evidence-Based Clinical Guidelines for Multidisciplinary Spine Care. Diagnosis and treatment of adult isthmic spondylolisthesis. https://www.spine.org. Published 2014.

75. North American Spine Society (NASS). Evidence-Based Clinical Guidelines for Multidisciplinary Spine Care. Diagnosis and treatment of cervical radiculopathy from degenerative disorders. https://www.spine.org. Published 2010.

76. North American Spine Society (NASS). Evidence-Based Clinical Guidelines for Multidisciplinary Spine Care. Diagnosis and treatment of degenerative lumbar spinal stenosis. https://www.spine.org. Published 2007. Updated 2011.

77. North American Spine Society (NASS). Evidence-Based Clinical Guidelines for Multidisciplinary Spine Care. Diagnosis and treatment of degenerative lumbar spondylolisthesis. https://www.spine.org. Published 2008. Updated 2014.

78. North American Spine Society (NASS). Evidence-Based Clinical Guidelines for Multidisciplinary Spine Care. Diagnosis and treatment of low back pain. https://www.spine.org. Published 2020.

79. North American Spine Society (NASS). Evidence-Based Clinical Guidelines for Multidisciplinary Spine Care. Diagnosis and treatment of lumbar disc herniation with radiculopathy. https://www.spine.org. Published 2012.

80. Schwab F, Mekhail N, Patel K, et al. Restorative neurostimulation therapy compared to optimal medical management: a randomized evaluation (RESTORE) for the treatment of chronic mechanical low back pain due to multifidus dysfunction. *Pain Ther.* 2025;14:401-423.

81. Tirado C, Washburn S, Covalin A, et al. Delivering transcutaneous auricular neurostimulation (tAN) to improve symptoms associated with opioid withdrawal: results from a prospective clinical trial. *Bioelectron Med.* 2022;8:12.

82. UpToDate, Inc. Complex regional pain syndrome in adults: treatment, prognosis, and prevention. https://www.uptodate.com. Updated January 2025.

83. UpToDate, Inc. Essential tremor: treatment and prognosis. https://www.uptodate.com. Updated January 2025.

84. UpToDate, Inc. Management of non-radicular neck pain in adults. https://www.uptodate.com. Updated January 2025.

85. UpToDate, Inc. Management of restless legs syndrome and periodic limb movement disorder in adults. https://www.uptodate.com. Updated February 4, 2025.

86. US Department of Veterans Affairs (VA). Clinical Practice Guideline. Diagnosis and treatment of low back pain. https://va.gov. Published February 2022.

87. US Department of Veterans Affairs (VA). Clinical Practice Guideline. Management of substance use disorders. https://va.gov. Published August 2021.

88. US Department of Veterans Affairs (VA). Clinical Practice Guideline. Nonsurgical management of hip and knee osteoarthritis. https://va.gov. Published July 2020.

89. US Food & Drug Administration (FDA). 510(k) summary: Axon Therapy. https://fda.gov. Published June 11, 2021.

90. US Food & Drug Administration (FDA). 510(k) summary: Cala Trio. https://fda.gov. Published October 5, 2021.

91. US Food & Drug Administration (FDA). 510(k) summary: ClearUP Sinus Pain Relief. https://fda.gov. Published January 2, 2019.

92. US Food & Drug Administration (FDA). 510(k) summary: Electro Auricular Device (EAD) (Neuro-Stim). https://fda.gov. Published October 2, 2014.

93. US Food & Drug Administration (FDA). 510(k) summary: Moventis PNS. https://fda.gov. Published August 14, 2020.

94. US Food & Drug Administration (FDA). 510(k) summary: Nalu Neurostimulation System. https://fda.gov. Published March 22, 2019.

95. US Food & Drug Administration (FDA). 510(k) summary: NeuroMetrix SENSUS. https://fda.gov. Published August 2, 2012.

96. US Food & Drug Administration (FDA). 510(k) summary: Neuspera Nuity System. https://fda.gov. Published April 11, 2023.

97. US Food & Drug Administration (FDA). 510(k) summary: Quell. https://fda.gov. Published January 4, 2016.

98. US Food & Drug Administration (FDA). 510(k) summary: Sprint System. https://fda.gov. Published June 26, 2017.

99. US Food & Drug Administration (FDA). 510(k) summary: STIMPOD NMS460 Nerve Stimulator. https://fda.gov. Published January 18, 2017.

100. US Food & Drug Administration (FDA). 510(k) summary: StimQ Peripheral Nerve Stimulator (PNS) System. https://fda.gov. Published March 11, 2016.

101. US Food & Drug Administration (FDA). 510(k) summary: StimRouter Neuromodulation System. https://fda.gov. Published March 27, 2020.

102. US Food & Drug Administration (FDA). 510(k) summary: UltraTENS. https://fda.gov. Published August 26, 2015.

103. US Food & Drug Administration (FDA). De novo summary: Cala ONE. https://fda.gov. Published April 26, 2018.

104. US Food & Drug Administration (FDA). De novo summary: IB-Stim. https://fda.gov. Published June 7, 2019.

105. US Food & Drug Administration (FDA). Summary of safety and effectiveness data: Altius Direct Electrical Nerve Stimulation System. https://fda.gov. Published August 26, 2024.

106. US Food & Drug Administration (FDA). Summary of safety and effectiveness data: ReActiv8 Implantable Neurostimulation System. https://fda.gov. Published June 16, 2020.

107. Xu J, Sun Z, Wu J, et al. Peripheral nerve stimulation in pain management: a systematic review. *Pain Physician.* 2021;24:E131-E152.

## Change Summary

01/01/2024 New Policy.
04/23/2024 Annual Review, Coverage Change.
10/08/2024 Provider Claims Codes Update, No Coverage Change.
12/10/2024 Update, No Coverage Change
01/03/2025 Provider Claims Codes Update, No Coverage Change.
05/01/2025 Annual Review, Coverage Change. Updated Coding Information