

Peripheral Nerve Stimulators



INDEPENDENT CARE HEALTH PLAN

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Medicare Advantage Medical Coverage Policy

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Related Medicare Advantage Medical/Pharmacy Coverage Policies

Headache and Occipital Neuralgia Treatments

Related Documents

Please refer to [CMS website](#) for the most current applicable National Coverage Determination (NCD)/ Local Coverage Determination (LCD)/Local Coverage Article (LCA)/CMS Online Manual System/ Transmittals.

Type	Title	ID Number	Jurisdiction Medicare Administrative Contractors (MACs)	Applicable States/Territories
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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 LCA	Peripheral Nerve Stimulation	L34328 A55530	JE - Noridian Healthcare Solutions, LLC	CA, HI, NV, American Samoa, Guam, Northern Mariana Islands
LCD LCA	Peripheral Nerve Stimulation	L37360 A55531	JF - Noridian Healthcare Solutions, LLC	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
LCA	Auricular Peripheral Nerve Stimulation (Electro-Acupuncture Device)	A55240	JH - Novitas Solutions, Inc. (Part A/B MAC) JL - Novitas Solutions, Inc. (Part A/B MAC)	AR, CO, NM, OK, TX, LA, MS DE, DC, MD, NJ, PA
LCD LCA	Transcutaneous Electrical Joint Stimulation Devices (TEJSD) Transcutaneous Electrical Nerve Stimulators (TENS)	L34821 A52713 L33802 A52520	DME A - Noridian Healthcare Solutions, LLC (DME MAC) DME B - CGS Administrators, LLC (DME MAC) DME C - CGS Administrators, LLC (DME MAC)	CT, DE, DC, ME, MD, MA, NH, NJ, NY, PA, RI, VT IL, IN, KY, MI, MN, OH, WI AL, AR, CO, FL, GA, LA, MS, NM, NC, OK, SC, TN, TX, VA, WV, PR, U.S. VI

			DME D - Noridian Healthcare Solutions, LLC (DME MAC)	AK, AZ, CA, HI, ID, IA, KS, MO, MT, NE, NV, ND, OR, SD, UT, WA, WY, American Samoa, Guam, Northern Mariana Islands
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Description

Stimulation of the peripheral nerves has been proposed as a method to treat a wide array of conditions, such as pain, nausea and vomiting or even recently has been proposed for essential tremors. 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. It is theorized that stimulation of the corresponding acupuncture points will relieve pain in various locations in the body. Examples of this type of device include, but may not be limited to, **Neuro-Stim System (NSS)** and **P-Stim** which are disposable, preprogrammed units worn behind the ear and connected to acupuncture needles.

Cala Trio was granted FDA clearance for treatment of hand tremors in adults with essential tremor. The device is worn on the wrist which 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 purported for use in pain control for conditions such as complex regional pain syndrome (also known as 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**, **iRelieve 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.

A variation of auricular electrostimulation is **percutaneous electrical nerve field stimulation (PENFS)**, which 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 **First Relief** system and the **Primary Relief** system. Both use auricular stimulation points for location of the electrodes. The First Relief 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.

Percutaneous implanted peripheral nerve stimulation is a further variation of PNT. The electrodes are implanted via a percutaneous, minimally invasive approach; when a 60 day treatment is completed, they are removed. Its purported use is for an individual with chronic and acute pain, including postoperative and post-traumatic pain. An example of this device includes, but may not be limited to, the **Sprint PNS system**, which utilizes either the **Sprint endura** (single lead) or the **Sprint extensa** (dual lead).

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 **Nalu Neurostimulation system** and **StimQ system**. 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 they 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 **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, the muscle will be strengthened, and the back pain will be decreased. 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, but may not be limited to, 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, except HVPG is proposed for the treatment of carpal 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 has been 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 US Food & Drug Administration (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**. A further variation of this technology is the **Venus Freedom** device, which delivers nonthermal radiofrequency energy combined with magnetic field pulse stimulation and massage; it is FDA-approved for treatment of minor muscle aches and pains, to relieve muscle spasms and temporarily improve local blood circulation.

Coverage Determination

iCare follows the CMS requirements that only allows 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.

Please refer to the above CMS guidance for **transcutaneous electrical nerve stimulators (TENS)** and **transcutaneous electrical joint stimulation devices**.

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the following criteria:

PENS

PENS will be considered medically reasonable and necessary when the following requirements are met:

- Diagnosis of chronic low back pain secondary to degenerative disc disease; **AND**
- Maximum 30 day treatment period; **AND**
- Treatment is performed by a healthcare provider in an office/clinic setting; **AND**
- Used as part of a comprehensive rehabilitation program, which would include medications (eg, NSAIDs, if medically appropriate and not contraindicated) and PT

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. 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](#)

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:

- Combination stimulation devices including, but not limited to:
 - ICS with muscle stimulators (NMES) including, but not limited to, the RS-4i Plus sequential stimulator; **OR**
 - TENS with ICS; **OR**
 - TENS with ICS and galvanic direct current continuous stimulation including, but not limited to, the Flex-MT Plus and Neufit Neubie; **OR**
 - TENS with ICS, microcurrent and NMES including, but not limited to, the InTENSity Select Combo; **OR**

- TENS with LLLT including, but not limited to, the Neurolumen device; **OR**
- TENS with NMES including, but not limited to, the Empi Phoenix and QB1 System; **OR**
- TENS with ultrasound device including, but not limited to, the UltraTENS; **OR**
- 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) including, but not limited to, the Hako-Med Pro ElecDT 2000; **OR**
- High frequency impulse therapy (HFIT) including, but not limited to, the ENSO; **OR**
- Percutaneous neuromodulation therapy including, but not limited to, the BioWaveGo, BioWaveHome or BioWavePRO; **OR**
- Sympathetic therapy; **OR**
- Transcutaneous auricular neurostimulation (tAN) (also known as transcutaneous nerve field stimulation) including, but not limited to, the Sparrow Therapy System; **OR**
- Transcutaneous magnetic stimulation (also known as therapeutic magnetic resonance [TMR]) including, but not limited to, Axon Therapy; **OR**
- Transcutaneous pulsed radiofrequency stimulation including, but not limited to, the STIMPOD NMS460 and Venus Freedom; **OR**
- Transdermal neuromodulation

A review of the current medical literature shows that there is no evidence to determine that this service is standard medical treatment. There is an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service 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:

- Auricular electrostimulation (also referred to as auricular electroacupuncture or pulsed stimulation) for any indication, (eg, treatment of pain associated with opiate withdrawal) including, but not limited to the following devices:
 - Neuro-Stim System (NSS); **OR**
 - P-Stim; **OR**

- H-wave stimulation; **OR**
- High-volt galvanic stimulation (HVPG or HVG); **OR**
- Interferential current stimulation (ICS) (interferential therapy) including, but not limited to, the neo-GEN Series system; **OR**
- Microcurrent electrical nerve stimulation (MENS) including, but not limited to, Alpha-Stim M, Electro-Myopulse 75L, iRelieve or Myopulse; **OR**
- Percutaneous electrical nerve field stimulation (PENFS) of the cranial nerves (without implantation) including, but not limited to, the following devices:
 - Bridge device for any indication including, but not limited to, pain associated with opioid withdrawal; **OR**
 - Drug Relief V1 device for any indication including, but not limited to, pain associated with opioid withdrawal; **OR**
 - First Relief system for any indication including, but not limited to, diabetic peripheral neuropathy; **OR**
 - IB-Stim stimulator for any indication including, but not limited to, IBS; **OR**
 - Morph device for any indication including, but not limited to, pain associated with opioid withdrawal; **OR**
 - Primary Relief system for any indication including, but not limited to, post cesarean section pain or post cardiac surgery pain; **OR**
- Percutaneous implanted peripheral nerve stimulation including, but not limited to, the Sprint endura, Sprint extensa or Sprint PNS system; **OR**
- Peripheral nerve field stimulation (PNFS) or peripheral subcutaneous field stimulation (PSFS) for ANY indication, including, but not limited to, trigeminal neuralgia or facial pain; **OR**
- Peripherally implanted nerve stimulation including, but not limited to, the Nalu Neurostimulation system or StimQ PNS system for ANY indication including, but not limited to, trigeminal neuralgia or facial pain; **OR**
- Permanent peripheral implantable neuromodulator including, but may not be limited to, the ReActiv8 or StimRouter system; **OR**
- Pulsed electrical stimulator (PES) including, but not limited to, the BioniCare Hand System, BioniCare Knee System or J-Stim 1000; **OR**

- Pulsed electromagnetic field therapy (PEMF) including, but not limited to, the OrthoCor Active System;
OR
- Scrambler therapy/Calmare pain therapy treatment (also known as transcutaneous electrical modulation pain reprocessing or TEMPR); **OR**
- Targeted pulsed electromagnetic therapy (tPEMF) including, but not limited to, the SofPulse tPEMF

A review of the current medical literature shows that the evidence is insufficient to determine that these services are standard medical treatments. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of these services in clinical management.

The **Cala Trio** will **not** be considered medically reasonable and necessary for any indication including, but not limited to, treatment of essential tremor. A review of the current medical literature shows that the evidence is insufficient to determine that this service is standard medical treatment. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management.

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

- Transcutaneous electrical acupoint stimulation including, but may not be limited to, the ReliefBand

A review of the current medical literature shows that the evidence is insufficient to determine that these services are standard medical treatments. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of these services in clinical management.

Summary of Evidence

Auricular Electrostimulation/Auricular Electroacupuncture

Hayes identified seven randomized controlled trials (RCT) evaluating the safety and effectiveness of the P-Stim device, which is used to deliver auricular electrostimulation. Their review of the findings in those studies revealed conflicting outcomes; compared to sham, three studies reported no improvement in pain or use of analgesic medication, and two additional studies reported an improvement with PStim for the treatment of chronic cervical pain and low back pain. Their final impression was that the overall quality of the evidence was low due to the limited number of studies and small patient populations.⁶³

Cala Trio

Hayes reported finding a minimal level of support in their review of full-text clinical studies, noting one poor quality RCT that suggested some benefits over sham after 1 treatment session, but did not establish any clear benefit or advantage over sham. No systematic reviews were identified.⁵¹ ECRI noted in their report

that the study findings do not permit conclusions as to whether clinical benefits are sustained beyond three months, as well as no studies compared the Cala Trio with other essential tremor treatments.²²

H-Wave Stimulation

Hayes, in their reports for the use of H-wave stimulation for treatment of low back pain and for lower extremity pain, found insufficient evidence to assess the safety and effectiveness of H-wave therapy for those indications. Most studies for this treatment are rather dated, and many were noted to have significant limitations in their methodology.^{73,74}

Interferential Current Stimulation (ICS)

The American College of Physicians (ACP), in their guideline for noninvasive treatments for acute, subacute, and chronic low back pain, noted that evidence was insufficient to determine the effectiveness of interferential therapy.⁸ UpToDate, in their report for subacute and chronic low back pain, concluded that there is no convincing evidence from three trials that interferential therapy is effective for chronic low back pain.⁹⁵

ECRI, in their report for ICS for conditions other than low back pain, reported on several studies, including systematic reviews; all noted limitations on generalization of results, low or very low quality of evidence and/or the need for further studies.³⁴

Microcurrent Electrical Nerve Stimulation (MENS)

Hayes concluded in their review 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.⁶¹

Percutaneous Electrical Nerve Field Stimulation (PENFS)

IB-Stim

Hayes found evidence from 1 fair-quality randomized sham-controlled trial with a subgroup analysis suggests 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. They concluded that a review of full-text clinical studies suggests no/unclear support for the IB-Stim device.⁵²

Bridge device

Hayes found minimal support in clinical studies in their review of the Bridge device, with only one very poor quality study identified, noting that it did not have comparison groups with placebo, sham, or active treatments. They concluded that while this study does suggest the Bridge device may alleviate symptoms of opioid withdrawal, 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.⁵⁰

Percutaneous Implanted Peripheral Nerve Stimulation

Sprint PNS system

ECRI identified a need for large multicenter RCTs to validate available data and to compare Sprint with other PNS systems as an evidence gap, as well as the current studies being at high risk of bias due to small sample size, single-center focus, retrospective design, and lack of controls or blinding.²⁸ Hayes noted that the evidence base is limited to 2 fair quality studies (in 3 publications) and 1 very poor quality study. Each study assessed Sprint PNS for a different source of chronic pain.⁵⁴

Peripheral Nerve Field Stimulation (PNFS)/Peripheral Subcutaneous Field Stimulation (PSFS)

Hayes found a very low quality body of evidence, which does not allow for conclusions regarding the efficacy and safety of PNFS for treatment of chronic low back pain (CLBP). While the limited evidence suggests that PNFS may provide statistically significant pain relief in refractory CLBP, it did not achieve clinical significance in all studies. Uncertainty exists due to limited evidence of comparative effectiveness relative to other interventions for CLBP and limited follow-up data. Additional studies are needed to evaluate the long-term efficacy and safety of PNFS versus comparable therapies, such as SCS, and definitive alternatives, such as surgery.⁵⁷

Peripherally Implanted Nerve Stimulation

Nalu Neurostimulation system

ECRI's review of this device led to a determination that the evidence is inconclusive, no data available; they were not able to identify any published studies that examined the safety and efficacy of the Nalu Neurostimulation system for treating chronic pain.²⁵

Stim Q

ECRI's review of this device led to a determination that the evidence is inconclusive, no evidence is available; they were not able to identify any published clinical studies or articles about the Stim Q device.³⁷

Permanent Peripheral Implantable Neuromodulator

StimRouter system

ECRI noted limited evidence from one, small, multicenter, randomized controlled trial (RCT) which suggested that StimRouter is safe, and it relieved chronic neuropathic pain and improved quality of life in slightly more than one-third of patients at three-month follow-up compared with sham treatment. However, they noted that additional RCTs are needed to validate results and to address other evidence gaps, such as comparisons to other pain management technologies.²⁹ Hayes, in their report, concluded that there was an insufficient quantity of published, peer-reviewed, human clinical data to evaluate the use of the StimRouter System for treatment of chronic pain.⁴⁸

ReActiv8 implantable device (restorative neurostimulation)

ECRI identified several evidence gaps in their report, including lack of RCTs comparing ReActiv8 with other pain management treatments, as well as need for longer-term (greater than 1 year) patient-oriented outcomes. Their conclusion that the evidence was inconclusive due to too few data on outcomes of interest, further noting that although one RCT reported ReActiv8 reduced pain in individuals with chronic intractable low back pain, the between-group differences in pain relief between it and sham was too small to be clinically significant.²⁷ Hayes had similar findings, with additional concern regarding identification of several adverse events, and mild and moderate adverse events found to be common, some of which led to the need for revision surgery and reimplantation. Their conclusion was minimal support for using ReActiv8 for chronic low back pain.⁵³

Pulsed Electrical Stimulator (PES)

According to Hayes, results of the available studies suggest that for patients who have osteoarthritis, PES can provide small-to-moderate improvements in knee pain and function. However, none of the available studies involved follow-up after treatment ended to determine the durability of benefits; therefore, additional studies are needed to determine whether the small-to-moderate benefits obtained with PES diminish after treatment ends.⁶⁰

Pulsed Electromagnetic Field Therapy (PEMF)

AHRQ 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. They also noted that more individuals who received PEMF versus sham reported throbbing or warming sensation, or aggravation of pain, though they did indicate that the difference was not statistically significant.² In another report, AHRQ identified 3 RCTs that assessed short-term effects of PEMF on pain due to knee osteoarthritis, noting that it had a statistically nonsignificant benefit on short-term pain based on a pooled analysis. They went on to note that evidence was insufficient to assess the effects of PEMF on short-term function or other outcomes.⁴

UpToDate noted that in a systematic review of PEMT in patients with neck pain of variable duration, there was low-quality evidence of minimal benefit (limited to immediate post-treatment pain relief) among those with chronic neck pain or whiplash syndrome.⁹³

Scrambler Therapy/Calmare Pain Therapy Treatment

A meta-analysis was conducted by Jin, Kim, Hur, and Myung regarding the efficacy of scrambler therapy for management of chronic pain. They 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. They 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.⁷⁶

Targeted Pulsed Electromagnetic Therapy (tPEMF)***SofPulse***

ECRI 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 they 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. They concluded that the evidence is inconclusive due to too few data.³⁶

Transcutaneous Electrical Acupoint Stimulation

ECRI reported on a systematic review by Matthews et al, which concluded that there was a lack of high quality evidence to support any intervention for treatment of nausea and vomiting in early pregnancy. They also reported on a systematic review by Cheong et al, which assessed postoperative nausea and vomiting

(PONV) interventions; they concluded that acupoint stimulation may be beneficial in prevention and treatment of PONV, and the evidence justifies future high-quality studies.³¹

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)	Description	Comments
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	
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
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	
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)	
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	

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Change Summary

- 01/01/2024 New Policy.