

01.01.37 Miscellaneous Electrical Stimulation for the Treatment of Pain

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Related Policies:

- [01.01.32 Electrical and Electromagnetic Stimulation for the Treatment of Arthritis](#)
- [01.01.33 Cranial Electrotherapy Stimulation and Auricular Electrostimulation](#)
- [01.01.34 Interferential Current Stimulation](#)
- [01.01.35 Non-Implantable Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy](#)
- [01.01.39 Remote Electrical Neuromodulation for Migraines](#)
- [07.01.78 Implantable Peripheral Nerve Stimulation and Restorative Neurostimulation for the Treatment of Chronic Pain](#)

Summary

Description

Electrical stimulation differs based on the device delivering the electrical stimulation, the device may provide direct, alternating, pulsating and/or pulsed waveforms of energy. The devices addressed in this evidence review will address miscellaneous electrical stimulation devices in the treatment chronic and/or acute pain which includes:

- Cefaly transcutaneous electrical stimulator (headband)
- Electroceutical therapy (also known as bioelectric nerve block)
- Electrotherapeutic point stimulation (ETPS)
- H-Wave electrical stimulation
- Transcutaneous low frequency pulsed magnetic stimulation (Axon Therapy Device)
- Microcurrent electrical nerve stimulation (MENS)
- Scrambler therapy (Calmare Therapy Device; also known as transcutaneous electrical modulation pain reprocessing [TEMPRT])

Note: For electrical stimulation not addressed in this evidence review see [Related Policies](#) above.

Summary of Evidence

For Individual who have chronic headache or migraines who receive Cefaly supraorbital transcutaneous electrical stimulation (TENS) in the treatment of acute migraine the evidence includes 3 double-blind, sham-controlled randomized controlled trials (RCTs). Two of the RCTs evaluated healthcare-provider administration of a Cefaly supraorbital TENS device during a single episode in emergency departments, and 1 evaluated self-administration of the device at home during acute episodes over a 3-month period. The studies conducted in emergency departments showed clinically and statistically significant reductions in pain intensity and medication use within 2 hours of use. The self-administration study had mixed results: The difference in median pain scores before and after treatment was significantly higher in the Cefaly supraorbital TENS group at months 1 and 2, but at month 3 the difference was not statistically significant. Function and analgesic medication use did not differ between groups at any time point. Strengths of the RCTs included the use of a sham device and blinded outcome assessment using validated outcome measures. Although short-term pain relief was demonstrated at some time points, the quality of the overall body of evidence was downgraded due to inconsistency of results and heterogeneity in study settings. It is not clear whether the pain intensity reductions demonstrated in emergency department settings would generalize to other settings over longer time periods. Supporting evidence from RCTs is needed. Additionally, based on the existing evidence, it is unclear how this Cefaly supraorbital TENS device would fit into the current migraine treatment pathway, although it could provide benefit for those who do not receive adequate benefit from pharmacologic first- or second-line therapies, or who may have a contraindication to pharmacologic therapies. The specific intended use must be specified in order to adequately evaluate net health benefit. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have chronic or episodic migraine who receive Cefaly supraorbital TENS for migraine prevention, the evidence includes 1 RCT. Relevant outcomes are symptoms, functional outcomes, QOL, and medication use. The RCT (N=67) reported a greater proportion of participants achieving at least a 50% reduction in migraines with Cefaly supraorbital TENS than with sham placebo and modest reductions in the number of total headache and migraine days. In the intention-to-treat analysis, the reduction in the number of migraine days (run-in vs. 3-months) was not statistically significant. The proportion of responders ($\geq 50\%$ reduction in the number of migraine days/month) significantly higher in

the Cefaly supraorbital TENS group. The number of migraine attacks from the run-in period to the 3-month evaluation, number of headache days, and antimigraine medication use were significantly lower for the active Cefaly supraorbital TENS group. The severity of migraine days did not differ significantly between groups. This manufacturer-sponsored trial needs corroboration before conclusions can be made with certainty about the efficacy of the Cefaly supraorbital TENS for preventing migraine headaches. Additionally, based on the existing evidence, it is unclear how this Cefaly supraorbital TENS device would fit into the current migraine prevention pathway, although it could provide benefit for those who do not receive adequate benefit from pharmacologic first- or second-line therapies, or who may have a contraindication to pharmacologic therapies. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have chronic and/or acute pain (e.g., musculoskeletal, neuropathic, and mixed pain conditions) who use these other miscellaneous electrical stimulation devices the current evidence includes small RCTs and case series studies. Relevant outcomes are symptoms, functional outcomes, QOL, and medication use. Although a few of these miscellaneous electrical stimulation devices have been evaluated in RCTs, these had important limitations such as precision, which preclude drawing strong conclusions about net health outcome. Further well-designed RCTs are needed to determine the benefits and harms of other miscellaneous electrical stimulation therapy in the treatment of individuals with chronic and/or acute pain. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

OBJECTIVE

The objective of the evidence review is to determine whether the application of miscellaneous electrical stimulation devices improves the net health outcome in individuals who suffer from chronic and/or acute pain.

PRIOR APPROVAL

Not applicable.

POLICY

Cefaly® supraorbital transcutaneous electrical stimulation is considered **investigational** for the prevention and treatment of migraine headaches because the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Electrical stimulation, including but not limited to the following is considered **investigational** for the treatment chronic and/or acute pain because the evidence is insufficient to determine that the technology results in an improvement in the net health outcome:

- Electroceutical therapy (also known as bioelectric nerve block)
- Electrotherapeutic point stimulation (ETPS)
- H-Wave electrical stimulation
- Transcutaneous low frequency pulsed magnetic stimulation (Axon Therapy)

- Microcurrent electrical nerve stimulation (MENS)
 - Algonix
 - Alpha-Stim 100
 - Electro-Mypulse 75L
 - Electro-Lyoscope 85P
 - KFH Energy
 - MENS 2000-D
 - Microcurrent or Myopulse 75C
- Scrambler therapy (Calmare pain therapy; also known as transcutaneous electrical modulation pain reprocessing [TEMPRT])

POLICY GUIDELINES

Coding

See the [Codes](#) table for details.

BACKGROUND

Cefaly Transcutaneous Electrical Stimulator (Headband)

The Cefaly supraorbital transcutaneous neurostimulation, classified as a transcutaneous electrical nerve stimulator (TENS), has FDA-approved indications which are limited to the prophylactic treatment of episodic migraine and treatment of acute migraine headaches (during a migraine attack), both of which are for individuals 18 years of age or older. The battery powered Cefaly supraorbital TENS device is a headband-like device that sits across the forehead (just above the eyes), applying an electric current to stimulate branches of the trigeminal nerve, which is thought to be associated with migraine headaches. The device purportedly works with neuromodulatory effects on those nerves, thereby blocking pain signals.

Electroceutical Therapy

Electroceutical medicine entails the use of various electrical modalities. While certain "low strength" electrical treatments such as TENS units may be safely used at home, electroceutical treatments use much higher electrical frequencies than TENS units (ranging from 1 to 20,000 Hz compared to 0.5 to 100 Hz used in TENS) and may only be prescribed and administered under the supervision of a healthcare provider experienced in this method of treatment.

Electroceutical therapy, also known as bioelectric nerve block, involves blockades of axonal transmissions. Electroceutical therapy has been used in the management of neuropathic pain (non-malignant pain) as well as pain associated with cancer (malignant pain). According to a manufacturer of an electroceutical nerve block device, the electroceutical treatment approach is based on the non-invasive application of controlled, specific parameter bioelectric impulses. Electrical current is altered via special step-down transformers into bioelectric impulses, which are designed to mimic the human bioelectric system. Currently, there are 2 distinctive electroceutical classifications:

1. stimulatory class in which repetitive action potentials are induced in excitable cells (depolarization and repolarization activity), and
2. multi-faciliatory class that produces biophysical effects without repetitive action potential propagation.

The proper electroceutical class, dosage, regimen duration and anatomical placement of electrodes are determined by the individual's diagnosis.

Electrotherapeutic Point Stimulation (ETPS)

Electrotherapeutic point stimulation (ETPS), also known as microcurrent point stimulation (MPS), employs a non-invasive device to administer low-frequency direct current to acupuncture points, motor/trigger points, and contracted muscle bands. The device (known as the ETPS 1000) has an enhanced point finder that detects treatment points on the skin and applies brief, concentrated electrical microstimulation in short bursts. This modality/approach combines the principles of acupuncture, massage, physical therapy and microcurrent stimulation. The treatment can be self-administered by the patient at home.

H-Wave Electrical Stimulation

H-Wave stimulation is a form of electrical stimulation that differs from other forms of electrical stimulation 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 (reflex sympathetic dystrophy), muscle sprains, temporomandibular joint dysfunctions or treatment of diabetic neuropathy.

Transcutaneous Low Frequency Pulsed Magnetic Stimulation

Transcutaneous low frequency pulsed magnetic stimulation, Axon Therapy (NeuraLace Medical Inc.) stimulates peripheral nerves using magnetic pulses to provide relief from chronic intractable pain for neuropathic origin. According to the manufacturer, Axon Therapy is a noninvasive therapy that delivers magnetic pulses to targeted peripheral nerve lesion where the pulses activate the A-beta sensory nerve fibers that work to suppress the pain signals transmitted to the lesion. The system consists of a figure 8-shaped coil connected to a compact stimulation module and a liquid cooling unit. The handheld coil is positioned directly over the targeted area or areas and delivers low frequency magnetic pulses (0 to 2 hertz [Hz]) for approximately 800 seconds. Treatment routinely consists of about 400 pulses. The annual treatment protocol consists of 16 treatments with concentrated sessions during the first month (up to 6 sessions) with monthly maintenance treatments.

Microcurrent Electrical Nerve Stimulation (MENS)

Microcurrent electrical nerve stimulation (MENS) devices are also non-invasive devices in which precise, tightly controlled electrical current is applied to specific points on the body. These specific points correspond with classical acupuncture points. MENS is also referred to as microelectrical therapy (MET) or microelectrical neuro-stimulation.

Scrambler Therapy

Scrambler therapy (also known as transcutaneous electrical modulation pain reprocessing or Calmare pain therapy) is an electro-cutaneous nerve stimulation device that interferes with pain signal transmission by mixing a "non-pain" information into the nerve fibers. It consists of a multi-processor apparatus capable of simulating 5 artificial neurons that send out signals identified by the central nervous system as "no pain" via the application of surface electrodes on skin in the pain areas.

Regulatory Status

In May 1998, Pro Eledt Series (Hako-Med) received FDA 510(k) clearance (K980892).

In February 2009, the Scrambler therapy MC-5A TENS Device (Competitive Technologies Inc.) was granted 510(k) classification (K081255) by the FDA indicated for "symptomatic relief of acute/chronic, intractable pain, post-surgical and post-traumatic acute pain." FDA product code: In December 2020, the Scrambler Therapy Technology (Model ST-5A) was granted 510(k) classification (K201548) by the FDA for Scrambler Therapy Technology (Model ST-5A). FDA product code: GZJ.

In May 2015, the Scrambler Therapy MC-5A Device (Delta International Services & Logistics S.r.l.) was granted 510(k) classification (K142666) by the FDA indicated for "symptomatic relief of acute/chronic, intractable pain, post-surgical and post-traumatic acute pain." FDA product code: GZJ

The H-Wave Muscle Stimulator device (Electronic Waveform Lab, Inc., Huntington Beach, CA) received FDA 510(k) clearance in 2011.

Microcurrent electrical nerve stimulation (MENS) devices are categorized as TENS devices intended for pain relief. The FDA regulates TENS under 21 Code of Federal Regulations 882.5890 as class II devices. Associated with product codes GZJ and JXK.

In 2014, the Cefaly® (STX-Med), which is a TENS device, was granted a de novo 510(k) classification by the FDA for the prophylactic treatment of migraine in patients 18 years of age or older. The Cefaly® Acute and Cefaly® Dual devices were cleared by the FDA through the 510(k) process for the acute treatment of migraine in patients in 18 years of age or older and for both the acute treatment and prophylaxis of migraines in adults, respectively, in 2017(K173006). In July 2024, Cefaly Connected was cleared by the FDA through the 510K process (K234029) in patients 18 years of age or older and for both the acute treatment and prophylaxis of migraines in adults.

In June 2021, Axon Therapy (NeuroLace Medical, Inc.) transcutaneous electrical nerve stimulator for pain relief was granted 510(k) classification (K210021) by the FDA. "The Axon Therapy is intended to stimulate peripheral nerves for relief of chronic intractable, post-traumatic and post-surgical pain for patients 18 and older." FDA product code: QPL

In January 2024, Axon Therapy (NeuroLace Medical, Inc.) transcutaneous electrical nerve stimulator for pain relief was granted 510(k) classification (K233364) by the FDA. "The Axon Therapy is indicated for relief of chronic painful diabetic peripheral neuropathy in the lower extremities." FDA product code: IPF

RATIONALE

This evidence review was created in October 2010 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through January 2026.

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life (QOL), and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Cefaly Supraorbital Device for Prevention and Treatment of Migraine

Clinical Context and Therapy Purpose

The purpose of Cefaly supraorbital transcutaneous electrical stimulation (TENS) (headband) device in individuals with migraine is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with episodic or chronic migraine.

Migraine is categorized as episodic or chronic depending on the frequency of attacks. Generally, episodic migraine is characterized by 14 or fewer headache days per month and chronic migraine is characterized by 15 or more headache days per month.

Specific International Classification of Headache Disorders diagnostic criteria are as follows:

- Episodic migraine:
 1. Untreated or unsuccessfully treated headache lasting 4 to 72 hours
 2. Headache has at least 2 of the following characteristics:
 1. Unilateral location
 2. Pulsating quality
 3. Moderate or severe pain intensity
 4. Aggravation by or causing avoidance of routine physical activity
 3. At least 1 of the following during headache:
 1. Nausea and/or vomiting
 2. Photophobia or phonophobia.

- Chronic migraine:
 1. Migraine-like or tension-type headache on 15 or more days per month for more than 3 months
 2. At least 5 headache attacks without aura meet episodic migraine criteria 1 to 3, and/or at least 5 headache attacks with aura meet episodic migraine criteria 2 to 3
 3. On more than 8 days per month for more than 3 months, fulfilling any of the following criteria:
 1. For migraine without aura, episodic migraine criteria 2 and 3
 2. For migraine with aura, episodic migraine criteria 1 and 2
 3. Believed by the patient to be migraine at onset and relieved by a triptan or ergot derivative.

Interventions

The therapy being considered is the Cefaly supraorbital TENS (headband) device for the prevention and treatment of migraine.

Comparators

The following therapies are currently being used to treat acute migraines due to episodic or chronic migraine: Medical management or no treatment. A number of medications are used to treat acute migraines. First-line therapy for mild or moderate migraine includes oral non-steroidal anti-inflammatory drugs (NSAIDs) or acetaminophen. More severe migraine can be treated through the use of triptans or an NSAID-triptan combination through a variety of routes (e.g., oral, nasal [spray or powder], subcutaneous). Antiemetics can be added for migraines accompanied by nausea or vomiting. Other pharmacologic interventions used to treat acute migraine include calcitonin-gene related peptide antagonists, which can be used in individuals with an insufficient response or contraindications to triptans, lasmiditan, and dihydroergotamine.

The following therapies are currently being used to prevent acute migraine in individuals with episodic or chronic migraine: medical management or no treatment. A number of medications are used as prevention for migraines. For most adults with episodic migraines who may benefit from preventive therapy, initial therapy with an antiepileptic drug (divalproex sodium, sodium valproate, topiramate) or beta-blockers (metoprolol, propranolol, timolol) is recommended. Frovatriptan may be beneficial as initial therapy for prevention of menstrually-associated migraine. Antidepressants (e.g., amitriptyline, venlafaxine), alternative beta-blockers (atenolol, nadolol), and additional triptans (naratriptan, zolmitriptan for menstrually-associated migraine prevention) may be considered if initial therapy is unsuccessful. For preventive treatment of pediatric migraine, many children and adolescents who received placebo in clinical trials improved and most preventive medications were not superior to placebo. Possibly effective preventive treatment options for children and adolescents may include amitriptyline, topiramate, or propranolol.

Outcomes

For treatment of acute migraine, specific important health outcomes include freedom from migraine pain and bothersome symptoms, restored function (e.g., return to normal activities), and patient-assessed global impression of treatment. Examples of relevant outcome measures appear in Table 1. Follow-up over several hours is needed to monitor for treatment effects.

For prevention of acute migraines in individuals with chronic or episodic migraine, specific important health outcomes include reduction of future attack frequency, severity, and duration, improved responsiveness to acute treatments, improved function and reduced disability, and prevention of progression of episodic migraine to chronic migraine. Follow-up over several days to months is needed to monitor for preventive treatment effects.

Table 1. Health Outcome Measures Relevant to Acute Migraine Attack

Outcome	Description
Pain free	No pain at defined assessment time (e.g., 2 hours)
Pain relief	Improvement of pain from moderate to severe at baseline to mild or none or pain scale improved at least 50% from baseline at defined assessment time (e.g., 2 hours)
Sustained pain free	No pain at initial assessment (e.g., 2 hours) and remains at follow-up assessment (e.g., 1 day) with no use of rescue medication or relapse (recurrence) within that time frame
Sustained pain relief	Improvement of pain from moderate to severe at baseline to mild or none or pain scale improved at least 50% from baseline at defined assessment time (e.g., 2 hours) and remains improved at follow-up assessment (e.g., 1 day) with no use of rescue medication or relapse (recurrence) within that time frame
Symptom relief	Improvement of most bothersome symptom(s) from moderate to severe at baseline to mild or none at defined assessment time (e.g., 2 hours)
Function relief	Improvement of function from moderate to severe at baseline to mild or none at defined assessment time (e.g., 2 hours)
Restored function	No restriction to perform work or usual activities at a defined assessment time (e.g., 2 hours)
Global impact of treatment	Patient assessment of functional disability and health-related quality of life using a Likert or other validated scale at a defined assessment time (e.g., 2 hours)
Global evaluation of treatment	Patient assessment of overall treatment effect (pain, symptom relief, adverse events) using a Likert or other validated scale at a defined assessment time (e.g., 2 hours)

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Migraine Treatment

Randomized Controlled Trials

Three double-blind, sham-controlled RCTs evaluated TENS for acute migraine treatment (Tables 2 and 3). Two of the studies evaluated healthcare-provider administration of the device during a single episode in emergency departments, and 1 evaluated self-administration of the device at home during acute episodes over a 3-month period.

Chou et al (2019) conducted an RCT of TENS to the trigeminal nerve with the Cefaly device in 106 individuals experiencing migraine headaches with or without aura. Eligibility criteria specified that participants may have used any acute medications to treat the attack, but not within the 3 hours before enrollment; 29% had treated the current migraine with an acute medication prior to enrollment. Patients received 1 hour of TENS or sham treatment. The primary outcome, mean pain intensity at 1 hour compared to baseline (using a VAS score of 0 to 10), improved by 3.46 ± 2.32 points in the TENS group versus 1.78 ± 1.89 points in the sham group ($p < .0001$). Patients without aura had significant improvement in pain intensity at 1 hour compared to sham ($p = .0006$) but there was no difference between treatments among patients with aura ($p = .06$). Seven minor adverse effects were reported, and there were no serious adverse events. Tables 2 and 3 summarize the key RCT characteristics and results related to this study.

Hokonek et al (2021) conducted a single center RCT (N=78) to evaluate the use of TENS in individuals presenting to an emergency department with a migraine. Participants had not received any medication prior to being admitted to the emergency department. Participants were randomized to TENS or a sham device, and their pain was assessed after 20 and 120 minutes. The change in VAS (0 to 100 mm) score from 0 to 20 min was -51.13 ± 2.94 for the TENS group, while the mean VAS score in the sham group was similar between baseline and 20 minutes (73 ± 3 vs. 72 ± 2). The change in VAS (0 to 100 mm) score from 0 to 120 min was -65 ± 25 for the TENS group and -9 ± 2 for the sham group ($p < .001$). Following randomization, 3 participants in the intervention group withdrew due to paresthesia caused by TENS administration and 2 in the control group withdrew due to severe pain; these individuals were not included in the analysis.

Domingues et al (2021) evaluated the analgesic efficacy of a portable, disposable, and home self-applied TENS device during migraine attacks. Participants (74 adults) who had been diagnosed with migraine by a specialist were randomized in this double-blind clinical trial to the active intervention (n=42) or a sham (n=32) with monthly follow-up for 3 months. The primary outcome measure was an evaluation of pain intensity following treatment. Subjects in both groups reported reduced pain scores; with significantly lower pain scores in the intervention group compared to the sham group ($p = .004$). Patients in the active intervention group also showed a significant improvement in functional disability scores. No adverse effects were reported.

Study limitations are summarized in Tables 4 and 5. Strengths of the RCTs included the use of a sham device and blinded outcome assessment using validated outcome measures. Although short-term pain relief was demonstrated at some time points, the quality of the overall body of evidence was downgraded due to inconsistency of results and heterogeneity in study settings. Supporting evidence from additional RCTs is needed.

Table 2. Summary of Key Randomized Controlled Characteristics

Study; Trial	Setting	Sites	Dates	Participants	Interventions	
					Active	Comparator
Chou et al (2019)	Emergency Departments, US	3	2016-2017	Adults (18 to 65 years of age) with IHS-defined acute migraine attack with or without aura for at least 3 hours before enrollment. Participants may have used any acute medications to treat the attack, but not within the 3 hours before enrollment. 29% had treated the current migraine with an acute medication prior to enrollment.	TENS (1 hour) with the Cefaly device (n=52)	Sham TENS (1 hour) using low-frequency pulses (n=54)
Hokonek et al (2021)	Emergency Department, Turkey	1	June-Oct 2019	Adults (ages 18 to 50 years) with IHS-defined migraine with or without aura, no preventive migraine treatment in the prior 30 days, presenting to the ED with an untreated acute migraine episode. Participants had not received any medication prior to being admitted to the ED.	TENS (20 minutes) (n=39)	Sham TENS using a device with an empty battery (20 minutes) (n=39)
Domingues et al (2021)	Home, Brazil	NR	Nov 2017-Jul 2018	Adults (18 to 65 years of age) with IHS-defined migraine with or without aura. Most participants were under pharmacological treatment for migraine but specifics of treatment for acute episodes during the study period were not reported.	TENS (20 minutes, self-applied at home) (n=42)	Sham TENS using a device with settings that did not meet those required for effective analgesic treatment by TENS devices (20 minutes, self-applied at home) (n=32)

ED: emergency department; IHS: International Headache Society; NR: not reported; RCT: randomized controlled trial; TENS: transcutaneous electrical nerve stimulation.

Table 3. Summary of Key Randomized Controlled Trial Results

Study	Pain score	Rescue medication use	Adverse Events
Chou et al (2019)	N=106	N=106	
TENS	Mean change After 1 hour: -3.46±2.32	After 2 hours: 6% After 24 hours: 40%	No serious adverse events.

Study	Pain score	Rescue medication use	Adverse Events
	After 2 hours: -2.87±2.24 After 24 hours: -3.46±2.65		Inability to tolerate paresthesia sensation: 2 discontinued before first 5 mins elapsed 3 discontinued before the full hour
Sham TENS	Mean change After 1 hour: -1.78±1.89 After 2 hours: -1.85±1.96 After 24 hours: -2.38±2.27	After 2 hours: 4% After 24 hours: 41%	1 discontinued before first 5 mins elapsed 1 discontinued before the full hour
p for difference	1 hour: <.0001 .2 hours: .028 24 hours: .062	After 2 hours: .66 After 24 hours: 1.0	
Hokonek et al (2021)	N=78	78	
	Likert-type verbal scale (1=severe pain, 5=more than fine)	Additional analgesic medication required at 120 minutes	
TENS	change in pain intensity 1 hour 4.5	1/39 (2.6%)	3/83 withdrew due to paresthesia caused by TENS administration
Sham TENS	mean at 1 hour 1.2	30/39 (76.9%)	2/83 withdrew due to severe pain
p	<.001	74.3%; 95% CI 59.9% to 87.6%)	
Domingues et al (2021)	N=74	N=74	
TENS	Median (IQR) Month 1: -3 (-10 to 0) Month 2: -2 (-10 to 0) Month 3: -2 (-10 to 0)	0 (0 to 3)	
Sham TENS	Median (IQR) Month 1: 0 (-7 to 0) Month 2: -2 (-10 to 0) Month 3: -2 (-10 to 0)	1 (9 to 5)	No adverse events or intolerance to the electrical stimuli
p for difference	Month 1: .001 Month 2: <.001 Month 3: .129	.427	No adverse events or intolerance to the electrical stimuli

CI: confidence interval; IQR: interquartile range; RCT: randomized controlled trial; TENS: transcutaneous electrical nerve stimulation.

Table 4. Study Relevance Limitations

Study	Population ^a	Intervention ^b	Comparator ^c	Outcomes ^d	Duration of Follow-up ^e
Chou et al (2019)	1. Intended use population is unclear (e.g., treatment naive, those with contraindications to medication, or those who have failed pharmacologic treatment)				
Hokonek et al (2021)	1. Intended use population is unclear (e.g., treatment naive, those with contraindications to medication, or those who have failed pharmacologic treatment)			Pain measure described as "likert-type verbal scale," unclear if validated	
Domingues et al (2021)	1, 2. Intended use population is unclear (e.g., treatment naive, those with contraindications to medication, or those who have failed pharmacologic treatment); no details on timing or type of treatment of acute attacks during the study period.				Follow-up was for 3 months. There was no difference between groups in pain score at the 3-month timepoint. Longer follow-up could provide more information about the effectiveness of the device over time.

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^a Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4. Enrolled populations do not reflect relevant diversity; 5. Other.

^b Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5. Other.

^c Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.

^d Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.

^e Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 5. Study Design and Conduct Limitations

Study	Allocation ^a	Blinding ^b	Selective Reporting ^c	Data Completeness ^d	Power ^e	Statistical ^f
Chou et al (2019)						

Hokonek et al (2020)		1. Authors stated that TENS patients probably felt that the unit was active	1. No mention of registration	5/83 randomized not included in analysis (3 TENS, 2 sham); no ITT analysis		Confidence intervals NR for pain scale difference; post hoc analysis for scores at different timepoints. Table 2 does not provide a footnote to explain data points and no statistical comparison. Text provides means and p-value for pain scores but does not specify timepoint.
Domingues et al (2021)						

ITT: intention-to-treat; NR: not reported; TENS: transcutaneous electrical nerve stimulation.

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^a Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4.

Inadequate control for selection bias; 5. Other.

^b Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.

^c Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.

^d Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials); 7. Other.

^e Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.

^f Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5. Other.

Migraine Prevention

Randomized Controlled Trial

One RCT evaluated TENS for acute migraine prevention in individuals with chronic or episodic migraine (Tables 11 and 12). The Cefaly device for prevention of migraine was evaluated in the Prevention of Migraine using the STS Cefaly (PREMICE) trial (2013).¹¹⁸ PREMICE was a double-blind, sham-controlled, randomized trial conducted at 5 tertiary care headache clinics in Belgium. Sixty-seven individuals with at least 2 migraine attacks per month were randomized to active (n=34) or sham (n=33) neurostimulation for 3 months, and 59 (88%) completed the trial on protocol. No serious adverse events occurred, although 1 patient discontinued the trial because of a reported device-caused headache. After a 1-month run-in period, patients were instructed to use the device daily for 3 months. Adherence was recorded by the TENS device. Ninety stimulation sessions were expected, but on average, 56 sessions were completed by the active group, and 49 were completed by the sham group. Primary outcome measures were changes in the number of migraine days and the percent of responders.

In the intention-to-treat analysis, the change in the number of migraine days (run-in vs. 3-month) was -2.06 (95% CI, -0.54 to -3.58) for the TENS group and 0.32 (95% CI, -0.63 to +1.27) for the sham group; this difference was not statistically significant (p=.054). The proportion of responders (≥50% reduction in the number of migraine days/month) was 38% (95% CI, 22% to 55%) in the TENS group and 12% (95% CI, 1% to 23%) in the sham group (p=.014). The number of migraine attacks from the run-in period to the 3-month evaluation was significantly lower for the active TENS group (decrease of 0.82 in the TENS group vs. 0.15 in the sham group; p=.044). The number of headache days was lower in the TENS group than in the sham group (decrease of 2.5 vs. 0.2; p=.041). Patients in the active TENS group reported a 36.6% reduction in the number of acute antimigraine drugs taken compared with a 0.5% reduction in the

sham group ($p=.008$). The severity of migraine days did not differ significantly between groups. No adverse effects were reported among the study participants. Study limitations are summarized in Tables 6 and 7.

Table 6. Summary of Key Randomized Controlled Trial Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Schoenen et al (2013); PREMICE,	Belgium	5	2009-2011	Adults (18 to 65 years of age) with IHS-defined migraine with or without aura and at least 2 migraine attacks per month	TENS (20 minutes daily) for 3 months (n=34)	Sham TENS (20 minutes daily) for 3 months (n=33)

HIS: International Headache Society; RCT: randomized controlled trial; TENS: transcutaneous electrical nerve stimulation.

Table 7. Summary of Key Randomized Controlled Trial Results

Study	Change in number of monthly migraine days at month 3	Responders at month 3	Change in antimigraine medication use at month 3
Schoenen et al (2013); PREMICE	N=67	N=67	N=67
TENS	-2.06 (-0.54 to -3.58)	38.24%	-36.6%
Sham TENS	0.32 (-0.63 to 1.27)	12.12%	0.5%
p	.054	.023	.0072

RCT: randomized controlled trial; TENS: transcutaneous electrical nerve stimulation.

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^a Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4.

Inadequate control for selection bias; 5. Other.

^b Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.

^c Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.

^d Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials); 7. Other.

^e Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.

^f Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5. Other.

Table 8. Study Relevance Limitations

Study	Population ^a	Intervention ^b	Comparator ^c	Outcomes ^d	Duration of Follow-up ^e
Schoenen et al (2013); PREMICE					1. Follow-up limited to 3 months

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^aPopulation key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4. Enrolled populations do not reflect relevant diversity; 5. Other.

^bIntervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5: Other.

^cComparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.

^dOutcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.

^eFollow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 9. Study Design and Conduct Limitations

Study	Allocation ^a	Blinding ^b	Selective Reporting ^c	Data Completeness ^d	Power ^e	Statistical ^f
Schoenen et al (2013); PREMICE			1. No mention of registration		4. Power calculated for a different outcome than the outcome described as primary	

Section Summary: Cefaly Supraorbital Device for Prevention and Treatment of Migraine

The evidence for the use of Cefaly supraorbital TENS for the treatment of acute includes 3 double-blind, sham-controlled RCTs. Two of the RCTs evaluated healthcare-provider administration of a Cefaly supraorbital TENS device during a single episode in emergency departments, and 1 evaluated self-administration of the device at home during acute episodes over a 3-month period. The studies conducted in emergency departments showed clinically and statistically significant reductions in pain intensity and medication use within 2 hours of use. The self-administration study had mixed results: The difference in median pain scores before and after treatment was significantly higher in the Cefaly supraorbital TENS group at months 1 and 2, but at month 3 the difference was not statistically significant. Function and analgesic medication use did not differ between groups at any time point. Strengths of the RCTs included the use of a sham device and blinded outcome assessment using validated outcome measures. Although short-term pain relief was demonstrated at some time points, the quality of the overall body of evidence was downgraded due to inconsistency of results and heterogeneity in study settings. It is not clear whether the pain intensity reductions demonstrated in emergency department settings would generalize to other settings over longer time periods. Supporting evidence from RCTs is needed. Additionally, based on the existing evidence, it is unclear how this Cefaly supraorbital TENS device would fit into the current migraine treatment pathway, although it could provide benefit for those who do not receive adequate benefit from pharmacologic first- or second-line therapies, or who may have a contraindication to pharmacologic therapies. The specific intended use must be specified in order to adequately evaluate net health benefit.

The evidence for the use of Cefaly supraorbital TENS device for prevention of acute migraine in individuals with chronic or episodic migraine includes 1 RCT (N = 67) that reported a greater proportion of

patients achieving at least a 50% reduction in migraines with Cefaly supraorbital TENS than with sham placebo. The RCT also reported modest reductions in the number of total headache and migraine days. This manufacturer-sponsored trial needs corroboration before conclusions can be made about the efficacy of Cefaly supraorbital TENS for preventing migraine headaches. Additionally, based on the existing evidence, it is unclear how this TENS device would fit into the current migraine prevention pathway, although it could provide benefit for those who do not receive adequate benefit from pharmacologic first- or second-line therapies, or who may have a contraindication to pharmacologic therapies.

Miscellaneous Electrical Stimulation for Chronic and/or Acute Pain

Clinical Context and Therapy Purpose

Electrical stimulation is to provide a treatment option that is an alternative to or an improvement on existing therapies in individuals with chronic and/or acute pain (e.g., musculoskeletal, neuropathic, and mixed pain conditions).

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with chronic and/or acute pain conditions (e.g., musculoskeletal, neuropathic, and mixed pain conditions).

Interventions

The therapy being considered is miscellaneous electrical stimulation devices in the treatment chronic and/or acute pain which includes:

- Electroceutical therapy (also known as bioelectric nerve block)
- Electrotherapeutic point stimulation (ETPS)
- H-Wave electrical stimulation
- Transcutaneous low frequency pulsed magnetic stimulation (Axon Therapy)
- Microcurrent electrical nerve stimulation (MENS) including but not limited to the following:
 - Algonix
 - Alpha-Stim 100
 - Electro-Mypulse 75L
 - Electro-Lyoscope 85P
 - KFH Energy
 - MENS 2000-D
 - Microcurrent or Myopulse 75C
- Scrambler therapy (Calmare Pain Therapy; also known as transcutaneous electrical modulation pain reprocessing [TEMPRT])

Comparators

The following therapies are currently being used to treat chronic and/or acute pain: physical therapy and pharmacotherapy.

Outcomes

The general outcomes of interest are reductions in symptoms and medication use, and improvements in functional outcomes and QOL. Given the different types of pain conditions, follow-up will vary, and some cases will be life-long.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Electroceutical Therapy (Bioelectric Nerve Block)

Note: Other terms used to refer to electroceutical therapy devices include “non-invasive neuron blockade” devices, “electroceutical neuron blockade” devices, and “bioelectric treatment systems.”

Review of Evidence

Electroceutical therapy (bioelectric nerve block) has been studied in management of neuropathic pain as well as pain associated with cancer (malignant pain). The current evidence is insufficient to support the efficacy of Electroceutical therapy (bioelectric nerve block) for any indication.

Electrotherapeutic Point Stimulation (ETPS)

Review of Evidence

Electrotherapeutic point stimulation (ETPS) is a handheld unit that generates low frequency DC electrical stimulation and releases body's endorphins which allow the body to naturally relieve pain, reduce stress levels and boost the immune system. It is also used for at home healing process, ETPS can replace common heat/cold therapies to use for treating injuries to reduce swelling (like code) and increasing blood flow (like heat). Conditions ETPS can be utilized for: muscles spasms, range of motion issues, fibromyalgia, chronic back pain, carpal tunnel, repetitive strain injuries and tension headaches/migraines.

The current evidence is insufficient to support the efficacy of electrotherapeutic point stimulation (ETPS) for any indication.

H-Wave Electrical Stimulation

Review of Evidence

H-Wave electrical stimulation devices have been investigated as a treatment for a variety of conditions including pain from diabetic peripheral neuropathy, muscle spasms, temporomandibular joint (TMJ) dysfunction, reflex sympathetic dystrophy, and healing of wounds such as diabetic peripheral ulcers.

Several randomized controlled trials (RCTs) have been published; however, the current evidence is insufficient to support the efficacy of H-wave electrical stimulation for any indication.

Transcutaneous Low Frequency Pulsed Magnetic Stimulation

Review of Evidence

Randomized Controlled Trial

In 2024, Kapural et al conducted a prospective, multi-site, randomized controlled trial comparing the long-term safety and efficacy of Axon Therapy (SEAT Study) in patients with chronic, intractable, post-traumatic or post-surgical peripheral neuropathic pain refractory to conservative therapy for a minimum of 3 months (pain medications, physical therapy, spinal and/or peripheral injection, pharmacological and behavioral treatment). After 7-day baseline assessment a total of 65 patients were included and were randomized in a 1:1 ratio and received magnetic peripheral nerve stimulation (mPNS [Axon Therapy]) along with conventional medical management (CMM) (AT+CMM) N=35 or CMM alone N=30. However, the per protocol population (PP) included 53 subjects (CMM+AT N=31 [10 male/21 females] and CMM N=23 [11 males/12 females]) as 10 subjects withdrew prior to the end of the study, one was lost to follow-up and another violated study protocol. Study subjects and investigators were not blinded to the assigned treatment group. The primary endpoint was a proportion of responders at day 90 with a 50% or greater reduction in pain based on visual analog score (VAS). The secondary endpoints included the European Quality of Life 5 Dimensions 3 Level (EQ-5D-3L) and Patient Global Impression of Change (PGIC). At 3 months, 71% of subjects were considered responders (>50% pain relief) in the mPNS + CMM group versus 13% of subjects in the CMM group ($p < 0.0001$). The mPNS + CMM group had a mean reduction in VAS scores at Day 90 of 3.8 points (>50% reduction), while CMM showed less than a 1-point (0.7 point) mean reduction or ~10% reduction ($p < 0.0001$). The EQ-5D-3L score increased in the mPNS + CMM study group, whereas the CMM group showed no improvement in EQ-5D-3L at Day 90. PGIC responder rates were 80.6% and 4.3% at Day 90 for mPNS + CMM and CMM groups, respectively. At day 90, subjects from CMM alone were offered the option to crossover to the treatment group, and continued to be followed by the study out to one year. Adverse events (AEs) were reported in two subjects in CMM+AT (1 subject with ankle pain and 1 subject with shoulder pain) both were unrelated to AT procedure. Limitations included small sample size, no sham control and lack of long term follow-up.

Section Summary: Transcutaneous Low Frequency Pulse Magnetic Stimulation

The current evidence includes one RCT. The study included small sample size, no sham control and lack of long-term follow-up. While the study may show promise additional comparative RCTs are needed with longer follow-up to determine the safety and efficacy of transcutaneous low frequency magnetic stimulation (Axon Therapy).

Microcurrent Electrical Stimulation (MENS)

Review of Evidence

Microcurrent electrical stimulation (MENS) has been studied for various pain syndromes. The current evidence includes several small RCTs and case series, however, the current evidence is insufficient to support the efficacy of microcurrent electrical stimulation (MENS) for any indication.

Scrambler Therapy

Review of Evidence

Systematic Review

In 2022, Karri et al performed a systematic review regarding the use of scrambler therapy (ST) in treatment chronic pain syndromes. Reviewers searched 4 databases (PubMed, EMBASE, Google Scholar and Clinicaltrials.gov) from 1950 through October 2021. Twenty-one studies met the final criteria for inclusion which included RCTS (n=8) (6 of these 8 studies were published after 2019), prospective observational studies (n=10), and retrospective cohort studies (n=3). These studies included small patient populations with only six of the studies including >50 subjects with most of the studies utilizing ST for the treatment of neuropathic pain, however, the majority of the high-quality evidence studied the use of ST in treating cancer-associated chronic pain with chemotherapy induced peripheral neuropathy (CIPN), rather than nonmalignant pain syndromes. The duration of post-treatment follow-up ranged from 10 to 14 days (consistent with completion of typical ST protocols) to 3-months. Treatment success was defined as $\geq$ 50% reduction in average pain scores relative to pre-procedure baseline, in which many subjects reported average pain reductions of up to 80% to 90%, but ST was found to be equivalent to sham therapy in two studies. Adverse events were reported in 17 of the studies and was considered safe and well tolerated with one reported adverse event of contact dermatitis. The studies included were found to have performance and detection biases and failed to evaluate additional outcomes aside from pain reduction and/or lacked clarity in reporting results. Also, authors of several of these studies reported industry affiliations with the manufacturer of the ST device, and the inventor of the ST device is an author of several studies. While these studies may suggest that ST may be beneficial for reducing pain further studies are needed to confirm these findings and also focus on the specific mechanism of ST electrode placement protocols.

Randomized Controlled Trial

In 2024, Stowell-Campos et al conducted a randomized single-blind sham controlled study evaluating the efficacy of scrambler therapy (ST) for the treatment of contralesional poststroke pain. Twenty patients with prior ischemic or hemorrhagic stroke found on neuroimaging with a positive finding of pain in the area(s) affected by their stroke were included. Ten (n=10) were randomized to receive ST (average age 60.0 years, 30% female and 30% Black), and ten (n=10) were randomized to Sham therapy (average age 56.9 years, 70% female and 60% Black) as an adjunct to their stable medication regimen. Participants underwent 5 consecutive daily 40-minute sessions. The study was blinded to patient and assessor; Pain scores were obtained and recorded at baseline prior to any neurostimulation using a dermatomal map and Numerical Rating Scale (0-10). Assessments were repeated prior to and after each session, and again 4 weeks following the intervention to determine long-term efficacy. Student's t-tests compared differences in the mean change in pain score between groups immediately post-treatment #5, and at 4-weeks. The chi-squared analyses compared the proportion of patients in each group with >50% pain reduction. Participants randomized to ST had a mean change in pain score of -3.73 (SD 2.85) postintervention and -2.57 (SD 2.07) at 4 weeks, while the Sham group had a mean change in score of

-0.94 (SD 1.36) and -0.25 (SD 0.84) (p between groups = 0.012, 0.0044, respectively). Significantly more participants treated with ST reported a >50% reduction in pain immediately post-intervention compared to Sham (70% versus 10%, p = 0.006), but not at follow-up (30% versus 10%, p = ns). Limitations include small sample size, participants treated at a single center and lack of long term follow-up.

Section Summary: Scrambler Therapy

The current evidence includes systematic reviews and RCTs. The studies included had small sample sizes, lack of long term follow-up and were found to have performance and detection biases and failed to evaluate additional outcomes aside from pain reduction and/or lacked clarity in reporting results. Also, authors of several of these studies reported industry affiliations with the manufacturer of the ST device, and the inventor of the ST device is an author of several studies. While these studies may suggest that ST may be beneficial for reducing pain further RCTs are needed to confirm these findings and also focus on the specific mechanism of ST electrode placement protocols.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review can be located at clinicaltrials.gov.

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CODES

To report provider services, use appropriate CPT codes, HCPCS codes, Revenue codes, and/or ICD diagnosis codes.

Codes	Number	Description
CPT		
	0278T	Transcutaneous electrical modulation pain reprocessing (e.g., Scrambler Therapy), each treatment session (includes placement of electrodes)
	0766T	Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, 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, 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)
HCPCS		
	E1399	Miscellaneous durable medical equipment
Type of Service	Durable Medical Equipment	
Place of Service	Outpatient/Home	

POLICY HISTORY

Date	Action	Action
February 2026	Annual Review	Policy Renewed
October 2025	Annual Review	Policy Renewed
October 2024	Annual Review	Policy Revised
October 2023	Annual Review	Policy Revised – content moved from retired policy “Electrical Stimulation for Treatment of Muscle Rehabilitation, Pain and Miscellaneous Conditions”
August 2022	Annual Review	Policy Revised

Date	Action	Action
December 2021	Interim Review	Policy Revised
August 2021	Annual Review	Policy Revised
July 2020	Annual Review	Policy Revised
July 2019	Annual Review	Policy Revised
August 2018	Annual Review	Policy Revised
August 2017	Annual Review	Policy Revised
August 2016	Annual Review	Policy Revised
September 2015	Annual Review	Policy Revised
November 2014	Annual Review	Policy Revised
January 2014	Annual Review	Policy Revised and New Policy Created
January 2013	Annual Review	Policy Renewed
January 2012	Annual Review	Policy Renewed
February 2011	Interim Review	Policy Revised
October 2010	Annual Review	Policy Renewed

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
PO Box 9232
Des Moines, IA 50306-9232

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