

Electrical Nerve Stimulation Devices

Policy # 00142

Original Effective Date: 02/01/2005

Current Effective Date: 03/10/2025

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services Are Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member’s contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider the use of transcutaneous electrical nerve stimulation (TENS) devices for the treatment of refractory chronic pain (e.g., chronic musculoskeletal or neuropathic pain) that causes significant disruption of function to be **eligible for coverage**.**

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of transcutaneous electrical nerve stimulation (TENS) for any other condition to be **investigational***, including but not limited for the following indications:

- Management of acute pain (e.g., postoperative or during labor and delivery)
- Treatment of dementia
- Prevention or treatment of migraine headaches
- Tinnitus
- Temporomandibular joint dysfunction (TMJ)
- Management of essential tremor
- Management of attention deficit hyperactivity disorder.

Based on review of available data, the Company considers transcutaneous afferent patterned stimulation (TAPS) for all indications, including but not limited the following conditions, to be **investigational:***

- Essential tremor;
- Action tremor for Parkinson disease;
- Dementia

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Based on review of available data, the Company considers the use of interferential current stimulation (IFS) to be **investigational**.*

Based on review of available data, the Company considers the use of H-wave stimulation for all applications to be **investigational**.*

Based on review of available data, the Company considers the use of threshold electrical stimulation as a treatment of motor disorders, including but not limited to cerebral palsy, and all other applications to be **investigational**.*

Based on review of available data, the Company considers the use of microcurrent stimulation for all applications to be **investigational**.*

Based on review of available data, the Company considers the use of galvanic stimulation for all applications to be **investigational**.*

When Services Are Not Covered

Based on review of available data, the Company considers form-fitting conductive garments, (e.g., vest, gauntlet, etc.), to be convenience items and not a covered benefit.

Policy Guidelines

For the purposes of these policy guidelines, refractory chronic pain is defined as pain that causes significant disruption of function and has not responded to at least 3 months of conservative therapy, including nonsteroidal anti-inflammatory medications, ice, rest, and/or physical therapy.

TENS devices may be delivered through a practitioner and require a prescription, or obtained without a prescription. It is possible that prescribed devices provide higher intensity stimulation than units sold directly to the public.

Background/Overview

The application of electrical stimulation creates the transfer of electrical energy. This transfer is responsible for the physiological changes which occur as a result of the clinical application of electrical stimulation. These changes occur at the cellular, tissue, segmental and systemic levels of the biological system and can be classified as electrothermal, electrochemical or electrophysical.

Electrothermal Reactions

The movement of charged particles in the conductive medium results in micro vibration of particles, causing minute frictional forces that eventually led to the production of heat.



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Electrochemical Reactions

Direct current application is most commonly associated with electrochemical reactions. The unidirectional flow caused by direct current re-distributes sodium and chlorine resulting in the formation of new compounds in the tissues under the electrodes. The normal reaction of the body to non-extensive chemical changes is to increase blood flow in order to restore tissue pH.

Electrophysical Reactions

The movement of ions results in the excitation of peripheral nerves and the stimulation of the movement of sodium and potassium ions across the cell membrane.

Transcutaneous Electrical Nerve Stimulation and Transcutaneous Afferent Patterned Stimulation

Transcutaneous electrical nerve stimulation (TENS) has been used to treat chronic intractable pain, migraine headache pain, postsurgical pain, and pain associated with active or post trauma injury unresponsive to other standard pain therapies. It has been proposed that TENS may provide pain relief through the release of endorphins in addition to potential blockade of local pain pathways. TENS has also been used to treat dementia by altering neurotransmitter activity and increasing brain activity that is thought to reduce neural degeneration and stimulate regenerative processes. Transcutaneous afferent patterned stimulation (TAPS) is a similar treatment used for essential tremor and action tremor due to Parkinson disease.

Percutaneous electrical nerve stimulation is similar to TENS but uses microneedles that penetrate the skin instead of surface electrodes. Interferential stimulation uses a modulated waveform for deeper tissue stimulation, and the stimulation is believed to improve blood flow to the affected area.

Interferential Stimulation (IFS)

Interferential current stimulation (IFS) is a type of electrical stimulation that has been investigated as a technique to reduce pain, improve function and range of motion, and treat gastrointestinal disorders.

This stimulation uses paired electrodes of 2 independent circuits carrying high-frequency and medium-frequency alternating currents. The superficial electrodes are aligned on the skin around the affected area. It is believed that IFS permeates tissues more effectively, with less unwanted stimulation of cutaneous nerves, and is more comfortable than transcutaneous electrical nerve stimulation. There are no standardized protocols for the use of IFS; IFS may vary by the frequency of stimulation, the pulse duration, treatment time, and electrode-placement technique.

H-Wave Stimulation

H-wave stimulation is a distinct form of electrical stimulation, and an H-wave device is U.S. Food and Drug Administration (FDA)-approved for medical purposes that involve repeated muscle contractions. H-wave electrical stimulation has been evaluated primarily as a pain treatment, but it



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has also been studied for other indications such as wound healing and improving post-surgical range of motion. Both office-based and home models of the H-wave device are available.

H-wave stimulation is a form of electrical stimulation that differs from other forms of electrical stimulation, such as TENS, in terms of its wave form. While H-wave stimulation may be performed by physicians, physiatrists, chiropractors, or podiatrists, H-wave devices are also available for home use. H-wave stimulation has been used for the treatment of pain related to a variety of etiologies, such as diabetic neuropathy, muscle sprains, temporomandibular joint dysfunctions, or reflex sympathetic dystrophy. H-wave stimulation has also been used to accelerate healing of wounds such as diabetic ulcers and to improve range of motion and function after orthopedic surgery.

H-wave electrical stimulation must be distinguished from the H-waves that are a component of electromyography.

Threshold Electrical Stimulation (TES)

TES is provided by a small electrical generator, lead wires, and surface electrodes that are placed over the targeted muscles. The intensity of the stimulation is set at the sensory threshold and does not cause a muscle contraction.

TES is described as the delivery of low-intensity electrical stimulation to target spastic muscles during sleep at home. The stimulation is not intended to cause muscle contraction. Although the mechanism of action is not understood, it is thought that low-intensity stimulation may increase muscle strength and joint mobility, leading to improved voluntary motor function. The technique has been used most extensively in children with spastic diplegia related to cerebral palsy but also in those with other motor disorders, such as spina bifida.

Microcurrent Stimulation

Microcurrent stimulation therapy involves the application of a very precise, low, tightly controlled electrical direct current to specific points on the body that correspond with classical acupuncture points. Unlike TENS, which blocks pain, microcurrent stimulation, usually at less than $600\mu A$, acts on the naturally occurring electrical impulses to decrease pain by stimulating the healing process through an increased production of adenosine triphosphate (ATP) levels. Any form of stimulation at 1,000 microamps causes an initial plateau and then a reduction of ATP.

Galvanic Stimulation

Galvanic stimulation is characterized by high voltage, pulsed stimulation and is used primarily for local edema reduction through muscle pumping and polarity effect. Edema is comprised of negatively charged plasma proteins, which leak into the interstitial space. The theory of galvanic stimulation is that by placing a negative electrode over the edematous site and a positive electrode at a distant site, the monophasic high voltage stimulus applies an electrical potential which disperses the negatively charged proteins away from the edematous site, thereby helping to reduce edema.



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FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Transcutaneous Electrical Nerve Stimulation and Transcutaneous Afferent Patterned Stimulation

TENS devices consist of an electrical pulse generator, usually battery-operated, connected by wire to 2 or more electrodes, which are applied to the surface of the skin at the site of the pain. Since 1977, a large number of devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. Marketing clearance via the 510(k) process does not require data on clinical efficacy; as a result, these cleared devices are considered substantially equivalent to predicate devices marketed in interstate commerce before May 1976, the enactment date of the Medical Device Amendments. The cleared devices are also equivalent to devices that have been reclassified and do not require a premarket approval application. FDA product code: GZJ.

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. Other TENS devices cleared by the FDA through the 510(k) process for the prophylactic treatment of migraine in patients include Allive (Nu Eyne Co), Relivion (Leurolief Ltd.) and HeadTerm (EEspress) among others. FDA product code: PCC.

In 2018, the FDA reviewed the Cala ONE^{™‡} TENS device (Cala Health) via the de novo pathway and granted approval for the device as an aid in the transient relief of hand tremors following stimulation in the affected hand of adults with essential tremor. This prescription device is contraindicated for use in patients with an implanted electrical medical device, those that have suspected or diagnosed epilepsy or other seizure disorder, those who are pregnant, and patients with swollen, infected, inflamed areas, or skin eruptions, open wounds, or cancerous lesions. In October 2020, the FDA granted breakthrough device designation to the Cala Trio^{™‡} device for the treatment of action tremors in the hands of adults with Parkinson's disease. In November 2022, the Cala kIQ^{™‡} device was approved via the 510(k) pathway (K222237). The device is indicated to aid in the temporary relief of hand tremors in the treated hand following stimulation in adults with essential tremor. It was also approved to aid in the temporary relief of postural and kinetic hand tremor symptoms that impact some activities of daily living in the treated hand of adults with Parkinson's disease. Cala Trio and Cala kIQ use transcutaneous afferent patterned stimulation (TAPS) therapy which consists of bursts of non-invasive electrical stimulation applied to the median and radial nerves.



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In 2019, the FDA permitted marketing of the first medical device to treat attention deficit hyperactivity disorder (ADHD) - the Monarch[®] external Trigeminal Nerve Stimulation (eTNS) System by NeuroSigma. The FDA reviewed the system through the de novo premarket review pathway. This prescription only TENS device is indicated for patients 7 to 12 years of age who are not currently taking prescription ADHD medication. The Monarch eTNS System is intended to be used in the home under the supervision of a caregiver. The device generates a low-level electrical pulse and connects via a wire to a small patch that adheres to a patient's forehead, just above the eyebrow.

In 2021, the FDA approved the Axon Therapy device (Neuralace Medical, Inc.) for marketing through the 510(k) process for relief of chronic, intractable postsurgical or posttraumatic pain in adults. The Axon Therapy device is an electromagnetic transcutaneous peripheral nerve stimulator. FDA product codes: QPL, IPF.

Interferential Stimulation (IFS)

A number of IFS devices have been cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process, including the Medstar[™] 100 (MedNet Services) and the RS-4i[®] (RS Medical). Interferential current stimulation may be included in multimodal electrotherapy devices such as transcutaneous electrical nerve stimulation and functional electrostimulation.

H-Wave Stimulation and Threshold Electrical Stimulation (TES)

In 1992, the H-Wave[®] muscle stimulator (Electronic Waveform Lab, Huntington Beach, CA) was cleared for marketing by the FDA through the 510(k) process. The U.S. FDA classified H-wave stimulation and TES devices as “powered muscle stimulators.” As a class, the FDA describes these devices as being “intended for medical purposes that repeatedly contracts muscles by passing electrical currents through electrodes contacting the affected body area.” According to the FDA, manufacturers may make the following claims regarding the effect of the device: “1) relaxation of muscle spasms; 2) prevention or retardation of disuse atrophy; 3) increasing local blood circulation; 4) muscle re-education; 5) immediate post-surgical stimulation of calf muscles to prevent venous thrombosis; and, 6) maintaining or increasing range of motion.”

Uses of the device not cleared by the FDA include, but are not limited to, treatment of diabetic neuropathy and wound healing.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.



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Transcutaneous Electrical Nerve Stimulation and Transcutaneous Afferent Patterned Stimulation

Transcutaneous electrical nerve stimulation and transcutaneous afferent patterned stimulation are noninvasive neuromodulation techniques that involve the application of electrical stimulation to the surface of the skin. In addition to more traditional settings such as a physician's office or an outpatient clinic, these techniques can be self-administered in an individual's home. Transcutaneous electrical nerve stimulation (TENS) describes the application of electrical stimulation to the surface of the skin. In addition to more traditional settings such as a physician's office or an outpatient clinic, TENS can be self-administered in an individual's patient's home.

Summary of Evidence

For individuals who have chronic pain (eg, musculoskeletal, neuropathic, and mixed pain conditions) who receive transcutaneous electrical nerve stimulation (TENS), the evidence includes numerous randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life (QOL), and medication use. The overall strength of the evidence is weak. The best evidence exists for the treatment of chronic, intractable pain. Available evidence indicates that TENS can improve chronic intractable pain in some patients, and there is support for its use in clinical guidelines by specialty societies. To best direct TENS toward patients who will benefit, a short-term trial of TENS is appropriate, with continuation only in patients who show an initial improvement. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have acute pain (eg, surgical, musculoskeletal, labor, and mixed pain conditions) who receive TENS, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, QOL, and medication use. Overall, evidence for the use of TENS from high-quality trials remains inconclusive for most indications. A systematic review of TENS for acute and chronic pain found some evidence that TENS reduces pain intensity over and above that seen with placebo and other control groups in patients with acute pain, but small-sized trials contributed to imprecision in magnitude estimates. Systematic reviews have found that TENS may help reduce pain in patients with post-operative pain (post-caesarean and total knee arthroplasty), dysmenorrhea, and pain associated with labor and delivery. For low back pain, systematic reviews have found insufficient evidence to support or refute the use of TENS. Randomized controlled trials have reported mixed results in the efficacy of TENS across various acute pain conditions. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have essential tremor who receive TAPSTENS, the evidence includes a pragmatic RCT, a nonrandomized, prospective study, and a retrospective database study. Relevant outcomes are symptoms, functional outcomes, QOL, and medication use. Although the RCT indicated reduced tremor power among patients receiving TAPS, the trial lacked thorough analysis of clinically relevant outcomes, was open-label, and short-term. Results from the nonrandomized



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study suggest that TAPSTENS therapy is effective and safe for patients with essential tremor. However, the trial was limited by its open-label, single-arm design, lack of defined standards for what constitutes a clinically meaningful improvement in stated endpoints, and exclusion of patients who exited the study early from the pre-specified primary and secondary endpoint analyses. Further studies comparing TAPSTENS to standard of care therapy for essential tremor are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have action tremor associated with Parkinson disease who receive TAPS, the evidence includes a prospective, open-label, single-arm study. Relevant outcomes are symptoms, functional outcomes, QOL, and medication use. Results of the prospective trial suggest that repeated in-home TAPS therapy is effective for reducing tremor power and safe for patients with essential tremor. Limitations identified were the open-label, single-arm design, and lack of long-term outcomes. Further studies comparing TAPS to pharmacologic therapy for tremor associated with Parkinson disease are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have attention deficit hyperactivity disorder (ADHD) who receive TENS, the evidence includes an RCT. Relevant outcomes are symptoms, functional outcomes, QOL, and medication use. Results of the RCT concluded that TENS is an effective and safe treatment option for pediatric patients with ADHD. However, the study included a small patient sample and was of short duration. Further studies comparing TENS to standard of care therapy for ADHD are needed. 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 TENS for treatment of acute migraine, the evidence includes 3 double-blind, sham-controlled RCTs. Two of the RCTs evaluated healthcare-provider administration of a 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 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 TENS would fit into the current migraine treatment pathway,



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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 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 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 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 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 TENS for preventing migraine headaches. Additionally, based on the existing evidence, it is unclear how TENS 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.

Interferential Stimulation (IFS)

Interferential current stimulation (IFS) is a type of electrical stimulation used to reduce pain. The technique has been proposed to decrease pain and increase function in individuals with osteoarthritis and to treat other conditions such as constipation, irritable bowel syndrome, dyspepsia, and spasticity.

For individuals who have musculoskeletal conditions who receive IFS, the evidence includes randomized controlled trials (RCTs) and meta-analyses. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Placebo-controlled randomized trial(s) have found that IFS when used to treat musculoskeletal pain and impaired function(s), does not significantly improve outcomes. Meta-analyses for IFS in musculoskeletal conditions have generally found IFS to be no more effective than other therapies. One network meta-analysis did find improvement with IFS compared with control, but the analysis is limited by indirect comparisons. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have gastrointestinal disorders who receive IFS, the evidence includes RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and



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treatment-related morbidity. Interferential current stimulation has been tested for a variety of gastrointestinal conditions, with a small number of trials completed for each condition. The results of the trials are mixed, with some reporting benefit and others not. This body of evidence is inconclusive on whether IFS is an efficacious treatment for gastrointestinal conditions. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have poststroke spasticity who receive IFS, the evidence includes RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The RCTs had small sample sizes and very short follow-up (immediately posttreatment to 5 weeks). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

H-Wave Stimulation

Most of the studies identified in searches evaluated H-wave stimulation for treating pain. As with other technologies intended to relieve pain, measurement of placebo effects is important and therefore the searches focused on placebo (sham)-controlled studies. Studies were also identified on H-wave stimulation for wound healing and post-surgical rehabilitation but not for other clinical applications of the technology.

Following is a summary of the key literature to date:

Pain treatment

In 2008, Blum and colleagues published a meta-analysis of studies evaluating the H-Wave device for treatment of chronic soft tissue inflammation and neuropathic pain. Five studies, 2 randomized controlled trials (RCTs) and 3 observational studies, met inclusion criteria. Four of the studies used a measure of pain reduction. In a pooled analysis of data from these 4 studies (treatment groups only), the mean weighted effect size was 0.59. Two studies reported the effect of the H-Wave device on pain mediation use; the mean weighted effect size was 0.56. (An effect size of 0.5 is considered a moderate effect and of 0.80 is considered a large effect.) A limitation of this analysis was that the authors did not use data from patients in the control or comparison groups; thus, the incremental effect of the H-Wave device beyond that of a comparison intervention cannot be determined.

The five studies identified by the systematic review for the meta-analysis were published by two research groups; Kumar and colleagues published three studies and the other two were published by Blum and colleagues. Blum and several co-investigators are consultants to the device manufacturer. Descriptions of the individual published studies are included below.

In 1997, Kumar and Marshall published an RCT comparing active H-wave electrical stimulation with sham stimulation for treatment of diabetic peripheral neuropathy. The authors selected 31 patients with type 2 diabetes and painful peripheral neuropathy in both lower extremities lasting at least 2 months. Patients were excluded if they had vascular insufficiency of the legs or feet or



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specified cardiac conditions. Patients were randomly assigned to the active group (n = 18) or the sham group (n = 13). Both groups were instructed to use their devices 30 minutes daily for 4 weeks. The device used in the sham group had inactive electrodes. Outcomes were assessed using a pain-grading scale (ranging from 0 to 5). Both groups experienced significant declines in pain, and the post-treatment mean grade for the active group was significantly lower than the mean grade for the sham group. This study did not state whether patients and/or investigators were blinded and did not state whether any patients withdrew from the study.

Another randomized study published by Kumar and colleagues in 1998 compared active H-wave electrical stimulation with sham stimulation among patients treated initially with a tricyclic antidepressant. The authors enrolled 26 patients with type 2 diabetes and painful peripheral neuropathy persisting for 2 months or more. Exclusion criteria were similar to those used in the earlier study. Amitriptyline was administered for 4 weeks initially, and those who had a partial response or no response were later randomly assigned to the 2 groups. After excluding 3 amitriptyline responders, the active stimulation group included 14 patients, and the sham stimulation included 9 patients. Sham devices had inactive output terminals. Stimulation therapy lasted 12 weeks, and final outcome assessment was conducted by an investigator blinded to group assignment 4 weeks after the end of treatment. As in the earlier study, mean pain grade in both groups improved significantly, but the difference between groups after treatment significantly favored active H-wave stimulation. Results on an analogue scale were similar. It is unclear whether patients were blinded to the type of device, and the report does not note whether withdrawals from the study occurred. A later report from this research group described a case series of 34 patients who continued H-Wave electrical stimulation for more than 1 year and achieved a 44% reduction in symptoms.

Two observational studies on the H-Wave device were published by Blum and colleagues and consisted of patients' responses to 3 of 10 questions on a manufacturer's customer service questionnaire (i.e., warranty registration card). In the larger of the two reports, 80% of 8,498 patients with chronic soft tissue injury and neuropathic pain who were given the H-Wave device completed the questionnaire. The answers were compared with an expected placebo response of 37% improvement. Following an average 87 days of use, 65% of respondents reported a decrease in the amount of medication needed, 79% reported an increase in function and activity, and 78% of respondents reported an improvement in pain of 25% or greater.

Wound healing

The only published study identified in literature searches was a case report from 2010 describing outcomes in 3 patients with chronic diabetic leg ulcers who used the H-Wave device.

Post-operative rehabilitation

In 2009, Blum and colleagues published a small double-blind placebo-controlled randomized trial evaluating home use of the H-Wave device for improving range of motion and muscle strength after rotator cuff reconstruction surgery. Electrode placement for the H-Wave device was done during the



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surgical procedure. After surgery, patients were provided with an active H-wave device (n = 12) or sham device (n = 10) and were instructed to use the device for 1 hour twice daily for 90 days. Individuals in the sham group were told not to expect any sensation from the device. Both groups also received standard physical therapy. At follow-up, range of motion of the involved extremity was compared to that of the uninvolved extremity. At the 90-day postoperative examination, patients in the H-wave group had significantly less loss of external rotation of the involved extremity (mean loss of 11.7 degrees) compared to the placebo group (mean loss of 21.7 degrees), $p = 0.007$. Moreover, there was a statistically significant difference in internal rotation, a mean loss of 13.3 degrees in the H-wave group and a mean loss of 23.3 degrees in the placebo group, $p = 0.006$. There were no statistically significant differences between groups in postoperative strength. The authors also stated that there was no statistically significant difference on any of the other 4 range-of-motion variables. The study did not assess change in functional status or capacity.

Summary

Two small controlled trials are insufficient to permit conclusions about the effectiveness of H-wave electrical stimulation as a pain treatment. Additional sham-controlled studies are needed from other investigators, preferably studies that are clearly blinded, specify the handling of any withdrawals, and provide long-term, comparative follow-up data. One small RCT represents insufficient evidence on the effectiveness of H-wave stimulation for improving strength and function after rotator cuff surgery. No comparative studies have been published evaluating H-wave stimulation to accelerate wound healing. In addition, no studies were identified that evaluated H-wave stimulation for any clinical application other than those described above. Thus, H-wave electrical stimulation is considered investigational.

Threshold Electrical Stimulation (TES)

Validation of therapeutic electrical stimulation requires randomized, controlled studies that can isolate the contribution of the electrical stimulation from other components of therapy. Physical therapy is an important component of the treatment of cerebral palsy and other motor disorders. Therefore, trials of threshold electrical stimulation ideally should include standardized regimens of physical therapy. Randomized studies using sham devices are preferred to control for any possible placebo effect.

A randomized study published in 1997 included 44 patients with spastic cerebral palsy who had undergone a selective posterior lumbosacral rhizotomy at least 1 year previously. All patients had impaired motor function, but some form of upright ambulation. Patients were randomly assigned to receive either a 12-month period of 8 to 12 hours of nightly electrical stimulation or no therapy. The principal outcome measure was the change from baseline to 12 months in the Gross Motor Function Measure (GMFM), as assessed by therapists blinded to the treatment. The patients and their parents were not blinded; the authors stated that the active device produced a tingling sensation that precluded a double-blind design. Patients were encouraged to maintain whatever ongoing therapy



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they were participating in. The type of physical therapy in either the control or treatment group was not described.

After 1 year, the mean change in the GMFM was 5.5% in the treated group, compared to 1.9% in the control group, a statistically significant difference. The authors state that this 3.6% absolute difference is clinically significant. For example, a child who was previously only able to rise and stand while pushing on the floor, could now do so without using hands. While these results point to a modest benefit, the lack of control for associated physical therapy limits the interpretation.

Five additional studies were identified in the literature over the next 10 years, none of them demonstrating effectiveness. Dali and colleagues published the results of a trial that randomly assigned 57 children with cerebral palsy to receive either threshold electrical stimulation or a dummy device for a 12-month period. Visual and subjective assessments showed a trend in favor of the treatment group, while there was no significant effect of therapeutic electrical stimulation in terms of motor function, range of motion, or muscle size. The authors concluded that therapeutic electrical stimulation was not shown to be effective in this study.

Two smaller randomized controlled studies found no improvement in muscle strength with electrical stimulation. In the van der Linden et al. study, 22 children with cerebral palsy were randomly assigned to receive 1 hour of electrical stimulation to the gluteus maximus daily over a period of 8 weeks to improve gait. No clinical or statistically significant between group differences were found in measurements of hip extensor strength, gait analysis, passive limits of hip rotation, and section E of the GMFM. Fehlings and colleagues also found no evidence of improved strength in 13 children with types II/III spinal muscular atrophy who were randomly assigned to either receive electrical stimulation or a placebo stimulator during a 12-month period. A study of 24 patients with cerebral palsy demonstrated positive results for the subset that received stimulation combined with dynamic bracing; however, the effect did not last after discontinuing treatment.

Kerr and colleagues randomly assigned 60 children with cerebral palsy to 1 hour daily of neuromuscular stimulation (n = 18), overnight threshold electrical stimulation (n = 20), or overnight sham stimulation (n = 22). Blinded assessment following 16 weeks of treatment showed no difference among the groups as measured by peak torque or by a therapist-scored gross motor function. A parental questionnaire on the impact of disability on the child and family showed improvement for the 2 active groups but not the sham control. Compliance in the threshold electrical stimulation group was 38%; compliance in the placebo group was not reported. Retrospective analysis indicated that the study would require 110 to 190 subjects to achieve 80% power for measures of strength and function.

A 2006 systematic review of electrical stimulation or other therapies given after botulinum toxin injection, conducted by the American Academy for Cerebral Palsy and Developmental Medicine, concluded that the available evidence is poor.



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Summary

The studies published to date demonstrate that threshold electrical stimulation is not effective for treatment of spasticity, muscle weakness, reduced joint mobility, or motor function; therefore, the treatment is considered investigational.

Supplemental Information

Transcutaneous Electrical Nerve Stimulation and Transcutaneous Afferent Patterned Stimulation

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.

American Academy of Neurology

In 2010, the American Academy of Neurology published an evidence-based review of the efficacy of transcutaneous electrical nerve stimulation (TENS) for the treatment of pain in neurologic disorders. The Academy did not recommend TENS for the treatment of chronic low back pain due to lack of proven efficacy (level A, established evidence from 2 class I studies), but stated that TENS should be considered for the treatment of painful diabetic neuropathy (level B, probably effective, based on 2 class II studies).

American College of Physicians

In 2017, the American College of Physicians published guidelines on noninvasive therapies for acute and low back pain.[Qaseem A, Wilt TJ, McLean RM, et al. Noninvasive T... 166(7): 514-530. PMID 28192789] No recommendations for TENS were made; the College concluded that “evidence was insufficient to determine the effectiveness” of TENS and that there was no long-range data.

American College of Rheumatology

In 2019, the American College of Rheumatology made a strong recommendation against the use of TENS for knee and hip osteoarthritis.

American Congress of Obstetricians and Gynecologists

In 2019 (reaffirmed in 2021), the ACOG guidelines on labor and delivery found that TENS may “help women cope with labor more than directly affect pain scores.”



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American Society of Anesthesiologists, et al

In 2010, the practice guidelines from the American Society of Anesthesiologists and American Society of Regional Anesthesia and Pain Medicine recommended that TENS be used as part of a multimodal approach to management for patients with chronic back pain and may be used for other pain conditions (eg, neck and phantom limb pain).

National Cancer Institute

The National Cancer Institute's Physician Data Query identifies TENS as a potential nonpharmacological modality for pain control for post thoracotomy pain syndrome.

National Comprehensive Cancer Network

National Comprehensive Cancer Network guidelines on adult cancer pain (v 2.20242023) indicate that nonpharmacologic interventions, including TENS, may be considered in conjunction with pharmacologic interventions as needed (category 2A).

National Institute for Health and Care Excellence

In 2016 (updated 2020), the NICE guidance on low back pain indicated that, despite the long history of use of TENS for back pain, the quality of research studies is poor. This guidance recommended against TENS as a treatment.

In 2014, the NICE guidance on osteoarthritis care and management in adults indicated that TENS be considered "as an adjunct to core treatments for pain relief." In 2022, NICE osteoarthritis guidelines recommend against TENS for osteoarthritis.

In 2017, the NICE guidance on intrapartum care recommended against the use of TENS for "established labour." In 2023, NICE recommendations for TENS included "there is very little evidence of its effectiveness in established labor, but no evidence of harm."

North American Spine Society

In 2020, the North American Spine Society clinical guidelines on the diagnosis and treatment of low back pain provided guidance on the effectiveness of different physical medicine and rehabilitation therapies. The guideline noted that there is conflicting evidence that TENS results in improvement in pain or function at short- to medium-term follow-up. The work group further recommended that randomized clinical trials with long-term follow-up are needed to evaluate the benefits of TENS compared to exercise/physical therapy or as adjunctive use to usual care for low back pain.

In 2011, the North American Spine Society clinical guidelines on the diagnosis and treatment of cervical radiculopathy from degenerative disorders discussed the role of ancillary treatments such as bracing, traction, electrical stimulation, acupuncture, and TENS. A consensus statement from the Society recommended that ozone injections, cervical halter traction, and combinations of medications, physical therapy, injections, and traction have been associated with improvements in



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patient-reported pain in uncontrolled case series. Such modalities may be considered, recognizing that no improvement relative to the natural history of cervical radiculopathy has been demonstrated. There were no specific statements about the role of TENS in this population.

Osteoarthritis Research Society International

In 2014, the guidelines from the Osteoarthritis Research Society International recommended that TENS was inappropriate for use in patients with multi-joint osteoarthritis; moreover, the guidelines suggested that TENS has an uncertain value for the treatment of knee-only osteoarthritis pain. Updated guidance (2019) on the non-surgical management of knee, hip, and polyarticular osteoarthritis does not address TENS nor include it in their patient-focused treatment recommendations.

World Health Organization

In 2023, the World Health Organization recommended against the use of TENS as part of routine care for patients with chronic low back pain. [World Health Organization. WHO guideline for non-s.... 89. Accessed October 15, 2024.] They found the net benefits across outcomes and comparators to be small or uncertain.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

The Centers for Medicare & Medicaid Services currently have a number of national coverage decisions on TENS. The different coverage decisions address the use of TENS in the treatment of chronic intractable pain, noncoverage of TENS for chronic low back pain except to conduct research for said indication, and coverage for acute postoperative pain.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT05939804	The Effect of Transcutaneous Electrical Nerve Stimulation (TENS) Application on Patients' Pain Level and Analgesic Use in Patients Undergoing Hip Replacement	60	Sep 2025 Jul 2024



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NCT05812885	Transcutaneous Electrical Nerve Stimulation (TENS) and Chronic Low-Back Pain: A Randomized Crossover Trial	34	Dec 2024
NCT05991921	The Effect of TENS Applied in the Early Postpartum Period on Incision Healing, Pain and Comfort	138	Aug 2023
NCT04114149	Effective Postoperative Pain Relief After Laparoscopic Cholecystectomy With TENS Treatment for First Line of Treatment Compared to Conventional Treatment With Opioids	166	Mar 2024
NCT05320432	Transcutaneous Electrical Nerve Stimulation for Pain Control During First Trimester Abortion: a Blinded Randomized Controlled Trial	70	Jan 2024
<i>Unpublished</i>			
NCT04092088	Effectiveness of Cerebral and Peripheral Electrical Stimulation on Pain and Functional Limitations Associated With Carpal Tunnel Syndrome: A Randomized, Double-blind, Multi-center, Factorial Clinical Trial	180	Oct 2020 (unknown status)
NCT05320432	Transcutaneous Electrical Nerve Stimulation for Pain Control During First Trimester Abortion: a Blinded Randomized Controlled Trial	72	Mar 2024 (published in abstract form)
NCT04851938	Evaluation of the Effect of Transcutaneous Electrical Nerve Stimulation Applied in Different Frequencies on Hormone Levels, Birth Pain Perception and Anxiety During Delivery	112	Jun 2021 (unknown status)
NCT02642796	Comparison of the Efficacy of 2 Different Transcutaneous Electrical Nerve Stimulation Application Sites in Reducing Postoperative Pain After Hip Fracture Surgery	120	Sep 2021

NCT: national clinical trial.



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Interferential Stimulation (IFS)

Practice Guidelines and Position Statements

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American College of Occupational and Environmental Medicine

The American College of Occupational and Environmental Medicine published several relevant guidelines. For shoulder disorders, guidelines found the evidence on interferential current stimulation (IFS) to be insufficient and, depending on the specific disorder, either did not recommend IFS or were neutral on whether to recommend it. For low back disorders, guidelines found the evidence on IFS to be insufficient and did not recommend it. For knee disorders, guidelines recommended IFS for postoperative anterior cruciate ligament reconstruction, meniscectomy, and knee chondroplasty immediately postoperatively in the elderly. This was a level C recommendation.

American College of Physicians and the American Pain Society

In 2009, the clinical practice guidelines from the American College of Physicians and the American Pain Society concluded that there was insufficient evidence to recommend IFS for the treatment of low back pain. An update of these guidelines by the American College of Physicians (2017) confirmed the 2009 findings that there was insufficient evidence to determine the effectiveness of IFS for the treatment of low back pain.

National Institute for Health and Care Excellence

In 2016, the National Institute for Health and Care Excellence published a guideline (NG59) on assessment and management of low back pain and sciatica in people aged 16 and over. The guideline states, "Do not offer interferential therapy for managing low back pain with or without sciatica."

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in April 2024 did not identify any ongoing or unpublished trials that would likely influence this review.



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H-Wave Stimulation and Threshold Electrical Stimulation (TES)

Centers for Medicare and Medicaid Services (CMS)

There is no national coverage determination for H-wave stimulation or TES.

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10/05/2004 Medical Director review

10/19/2004 Medical Policy Committee review. Policy replaces TENS policy. Additional modalities addressed: Interferential Stimulation, H-Wave Stimulation, Threshold Stimulation Microcurrent Stimulation, Galvanic Stimulation.



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11/29/2004 Managed Care Advisory Council approval. Policy to be effective for claims processing 02/01/2005.

04/14/2005 Policy History revised to reflect claims processing effective date.

10/05/2005 Medical Director review

10/18/2005 Medical Policy Committee review. Format revision. Coverage eligibility unchanged.

10/27/2005 Quality Care Advisory Council approval

10/04/2006 Medical Director review

10/18/2006 Medical Policy Committee approval. Format revision; updated with additional references. Coverage eligibility unchanged.

11/07/2007 Medical Director review

11/15/2007 Medical Policy Committee approval. No change to coverage eligibility.

12/03/2008 Medical Director review

12/17/2008 Medical Policy Committee approval. No change to coverage eligibility.

12/04/2009 Medical Policy Committee approval

12/16/2009 Medical Policy Implementation Committee approval. No change to coverage eligibility.

12/01/2010 Medical Policy Committee review

12/15/2010 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

03/01/2012 Medical Policy Committee review

03/21/2012 Medical Policy Implementation Committee approval. Management of postoperative pain bullet was removed from investigational indications.

03/07/2013 Medical Policy Committee review

03/20/2013 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

12/12/2013 Medical Policy Committee review

12/18/2013 Medical Policy Implementation Committee approval. Coverage eligibility unchanged. Processing changes only.

01/08/2015 Medical Policy Committee review

01/21/2015 Medical Policy Implementation Committee approval. Added Prevention of migraine headaches as investigational for TENS. Changed Interferential Current Stimulation investigational only.

01/07/2016 Medical Policy Committee review

01/22/2016 Medical Policy Implementation Committee approval. No change to coverage.

01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes

01/05/2017 Medical Policy Committee review

01/18/2017 Medical Policy Implementation Committee approval. No change to coverage.

01/04/2018 Medical Policy Committee review



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01/17/2018 Medical Policy Implementation Committee approval. Added a not covered section, and added Tinnitus, and Temporomandibular joint dysfunction (TMJ) as investigational for TENS.

01/10/2019 Medical Policy Committee review

01/23/2019 Medical Policy Implementation Committee approval. No change to coverage.

01/03/2020 Medical Policy Committee review

01/08/2020 Medical Policy Implementation Committee approval. No change to coverage.

01/07/2021 Medical Policy Committee review

01/13/2021 Medical Policy Implementation Committee approval. No change to coverage.

02/03/2022 Medical Policy Committee review

02/09/2022 Medical Policy Implementation Committee approval. Essential tremor and ADHD indications added as investigational for TENS.

02/02/2023 Medical Policy Committee review

02/08/2023 Medical Policy Implementation Committee approval. Changes made to TENS coverage. Added Policy Guidelines.

12/12/2023 Coding update

02/01/2024 Medical Policy Committee review

02/14/2024 Medical Policy Implementation Committee approval. Clarified that TENS is investigational for both prevention and treatment of migraine headache.

02/06/2025 Medical Policy Committee review

02/12/2025 Medical Policy Implementation Committee approval. For the TENS section, separated action tremor associated with Parkinson disease from essential tremor. Added new policy statements to differentiate TAPS as investigational for both essential tremor and action tremor associated with Parkinson disease.

Next Scheduled Review Date: 02/2026

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)†, copyright 2024 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	95972
HCPCS	A4541, C1883, E0731, E0733, E0744, E0745, S8130, S8131
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and



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- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

