Electrical Nerve Stimulation Devices

Policy # 00142
Original Effective Date: 02/01/2005
Current Effective Date: 01/08/2020

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 musculoskeletal pain 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) to be **investigational*** for the following indications:

- To relieve the pain of labor and vaginal delivery; or
- For the treatment of dementia.
- Prevention of migraine headaches
- Tinnitus
- Temporomandibular joint dysfunction (TMJ)

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.***

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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.

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.

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.

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Transcutaneous Electrical Nerve Stimulation (TENS)
Transcutaneous electrical nerve stimulation describes the application of electrical stimulation to the surface of the skin at the site of pain. Transcutaneous electrical nerve stimulation may be applied in a variety of settings (in the patient's home, a physician's office, or in an outpatient clinic).

Transcutaneous electrical nerve stimulation has been used to treat chronic intractable 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 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.

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.

IFS uses paired electrodes of two 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 the tissues more effectively and with less unwanted stimulation of cutaneous nerves, 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 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*u*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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Transcutaneous Electrical Nerve Stimulation (TENS)
U.S. Food and Drug Administration (FDA)
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 received marketing clearance through the U.S. FDA 510(k) process. Marketing clearance via the 510(k) process does not require data regarding clinical efficacy; these devices are considered substantially equivalent to predicate devices marketed in interstate commerce before May 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified and do not require approval of a premarket approval application.

On March 11, 2014, FDA granted de novo 510(k) approval for marketing to Cefaly®‡ (STX-med, Herstal, Belgium), which is a TENS device for the prophylactic treatment of migraine in patients 18 years of age or older.

The Centers for Medicare and Medicaid Services (CMS) currently have the following national coverage decisions on TENS:

- National Coverage Determination (NCD) for Transcutaneous Electrical Nerve Stimulators (TENS) (280.13)

TENS is a type of electrical nerve stimulator that is employed to treat chronic intractable pain. This stimulator is attached to the surface of the patient's skin over the peripheral nerve to be stimulated. It may be applied in a variety of settings (in the patient's home, a physician's office, or in an outpatient clinic). Payment for TENS may be made under the durable medical equipment benefit. Also see NCDs on Supplies Used in the Delivery of TENS and NMES (§160.13) and TENS for Acute Post-Operative Pain (§10.2).

- Decision Memo for Transcutaneous Electrical Nerve Stimulation for Chronic Low Back Pain (CAG-00429N)

In June 2012, CMS determined that TENS is not reasonable and necessary for the treatment of chronic low back pain. However, to support further research on the use of TENS for chronic low back pain, CMS will provide coverage under evidence development for a period of 3 years after the publication of this decision.

- National Coverage Determination for Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy (160.7.1)

Electrical nerve stimulation is an accepted modality for assessing a patient's suitability for ongoing treatment with a transcutaneous or an implanted nerve stimulator. Accordingly, program payment may be made for the following techniques when used to determine the potential therapeutic usefulness of an electrical nerve stimulator:

A. Transcutaneous Electrical Nerve Stimulation

This technique involves attachment of a transcutaneous nerve stimulator to the surface of the skin over the peripheral nerve to be stimulated. It is used by the patient on a trial basis and its effectiveness in modulating pain is monitored by the physician, or physical therapist. Generally, the physician or physical therapist is able to determine whether the patient is likely to derive a significant therapeutic benefit from continuous use of a transcutaneous stimulator within a trial period of 1 month; in a few cases this determination may take longer to make. Document the medical necessity for such services which are furnished beyond the first month. (See §160.13 for an explanation of coverage of medically necessary supplies for the effective use of TENS.) If TENS significantly alleviates pain, it may be considered as primary treatment; if it produces no relief or greater discomfort than the original pain electrical nerve stimulation therapy is ruled out. However, where TENS produces incomplete relief, further evaluation with percutaneous electrical nerve stimulation may be considered to determine whether an implanted peripheral nerve stimulator would provide significant relief from pain.

Usually, the physician or physical therapist providing the services will furnish the equipment necessary for assessment. Where the physician or physical therapist advises the patient to rent the TENS from a supplier during the trial period rather than supplying it himself/herself, program payment may be made for rental of the TENS as well as for the services of the physician or physical

therapist who is evaluating its use. However, the combined program payment which is made for the physician's or physical therapist's services and the rental of the stimulator from a supplier should not exceed the amount which would be payable for the total service, including the stimulator, furnished by the physician or physical therapist alone.

- National Coverage Determination for Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation (NMES) (160.13)

Transcutaneous electrical nerve stimulation and/or NMES can ordinarily be delivered to patients through the use of conventional electrodes, adhesive tapes and lead wires. There may be times, however, where it might be medically necessary for certain patients receiving TENS or NMES treatment to use, as an alternative to conventional electrodes, adhesive tapes and lead wires, a form-fitting conductive garment (i.e., a garment with conductive fibers which are separated from the patients' skin by layers of fabric).

A form-fitting conductive garment (and medically necessary related supplies) may be covered under the program only when:

1. It has received permission or approval for marketing by the Food and Drug Administration;
2. It has been prescribed by a physician for use in delivering covered TENS or NMES treatment; and
3. One of the medical indications outlined below is met:
    - The patient cannot manage without the conductive garment because there is such a large area or so many sites to be stimulated and the stimulation would have to be delivered so frequently that it is not feasible to use conventional electrodes, adhesive tapes and lead wires;
    - The patient cannot manage without the conductive garment for the treatment of chronic intractable pain because the areas or sites to be stimulated are inaccessible with the use of conventional electrodes, adhesive tapes and lead wires;
    - The patient has a documented medical condition such as skin problems that preclude the application of conventional electrodes, adhesive tapes and lead wires;
    - The patient requires electrical stimulation beneath a cast either to treat disuse atrophy, where the nerve supply to the muscle is intact, or to treat chronic intractable pain; or

- The patient has a medical need for rehabilitation strengthening (pursuant to a written plan of rehabilitation) following an injury where the nerve supply to the muscle is intact.

A conductive garment is not covered for use with a TENS device during the trial period specified in §160.3 unless:

1. The patient has a documented skin problem prior to the start of the trial period; and
2. The carrier's medical consultants are satisfied that use of such an item is medically necessary for the patient.

- National Coverage Determination for Transcutaneous Electrical Nerve Stimulation (TENS) for Acute Post-Operative Pain (10.2)

The use of TENS for the relief of acute post-operative pain is covered under Medicare. TENS may be covered whether used as an adjunct to the use of drugs, or as an alternative to drugs, in the treatment of acute pain resulting from surgery. TENS devices, whether durable or disposable, may be used in furnishing this service. When used for the purpose of treating acute post-operative pain, TENS devices are considered supplies. As such they may be hospital supplies furnished inpatients covered under Part A, or supplies incident to a physician's service when furnished in connection with surgery done on an outpatient basis, and covered under Part B. It is expected that TENS, when used for acute post-operative pain, will be necessary for relatively short periods of time, usually 30 days or less. In cases when TENS is used for longer periods, contractors should attempt to ascertain whether TENS is no longer being used for acute pain but rather for chronic pain, in which case the TENS device may be covered as durable medical equipment as described in §280.13.

Interferential Stimulation (IFS)
U.S. Food and Drug Administration (FDA)
A number of interferential stimulator devices have received 510(k) marketing clearance from the FDA, including the Medstar™‡ 100 (MedNet Services) and the RS-4i®‡ (RS Medical). IFS may be included in multimodal electrotherapy devices such as transcutaneous electrical nerve stimulation and functional electrostimulation.

Centers for Medicare and Medicaid Services (CMS)
There is no national coverage determination.

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H-Wave Stimulation and Threshold Electrical Stimulation (TES)
U.S. Food and Drug Administration (FDA)
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.

Centers for Medicare and Medicaid Services (CMS)
There is no national coverage determination for H-wave stimulation or TES.

Rationale/Source

Transcutaneous Electrical Nerve Stimulation (TENS)
This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. FDA approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, Blue Cross and Blue Shield Association technology assessment program (TEC) and other non-affiliated technology evaluation centers, reference to federal regulations, other plan medical policies and accredited national guidelines.

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 patients 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. The 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; additionally, a meta-analysis of placebo-controlled trials did not find a significant benefit of IFS for decreasing pain or improving function. The evidence is insufficient to determine the effects of the technology on health outcomes. For individuals who have gastrointestinal disorders who receive IFS, the evidence includes RCTs. The relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. IFS 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 the effects of the technology on health outcomes.

For individuals who have post stroke spasticity who receive IFS, the evidence includes an RCT. The relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The RCT had a small sample size and very short follow-up (immediately post treatment). The evidence is insufficient to determine the effects of the technology on health outcomes.

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 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 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 simulation 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 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.

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**.**

References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "Transcutaneous Electrical Nerve Stimulation (TENS)", 1.01.09, 12:2019.
2. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "Interferential Current Stimulation", 1.01.24, 07:2019.
3. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "H-wave Electrical Stimulation", 1.01.13, 11:2012.(Archived)
4. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "Threshold Electrical Stimulation as a Treatment of Motor Disorders", 1.01.19, 11:2013.(Archived)
5. Centers for Medicare and Medicaid. National Coverage Determination for Transcutaneous Electrical Nerve Stimulators (TENS) (280.13). 1995. Available online at: http://www.cms.gov/medicare-coverage-database/search/document-id-search-results.aspx?DocID=280.13&bc=gAAAAAAAAAAA&
6. Centers for Medicare and Medicaid. National Coverage Determination for Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy (160.7.1) 2006. Available online at: http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=63&ncdver=2&DocID=160.7.1&bc=gAAAAAgAAAAA&
7. Centers for Medicare and Medicaid. National Coverage Determination for Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation (NMES) (160.13) 1988. Available online at: http://www.cms.gov/medicare-coverage-database/search/document-id-search-results.aspx?DocID=160.13&bc=gAAAAAAAAAAA&
8. Medicare CfMa. National Coverage Determination for Transcutaneous Electrical Nerve Stimulation (TENS) for Acute Post-Operative Pain (10.2) 1995. Available online at:

http://www.cms.gov/medicare-coverage-database/search/document-id-search-results.aspx?DocID=10.2&bc=gAAAAAAAAAAA&

9. Centers for Medicare and Medicaid. Decision Memo for Transcutaneous Electrical Nerve Stimulation for Chronic Low Back Pain (CAG-00429N) 2012. Available online at: http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=256.
10. Fuentes JP, Armijo Olivo S, Magee DJ et al. Effectiveness of interferential current therapy in the management of musculoskeletal pain: A systematic review and meta-analysis. Phys Ther 2010; 90(9):1219-38.
11. Defrin R, Ariel E, Peretz C. Segmental noxious versus innocuous electrical stimulation for chronic pain relief and the effect of fading sensation during treatment. Pain 2005; 115(1-2):152-60.
12. Taylor K, Newton RA, Personius WJ et al. Effects of interferential current stimulation for treatment of subjects with recurrent jaw pain. Phys Ther 1987; 67:346-50.
13. Atamaz FC, Durmaz B, Baydar M et al. Comparison of the efficacy of transcutaneous electrical nerve stimulation, interferential currents, and shortwave diathermy in knee osteoarthritis: a double-blind, randomized, controlled, multicenter study. Arch Phys Med Rehabil 2012; 93(5):748-56.
14. Facci LM, Nowotny JP, Tormem F et al. Effects of transcutaneous electrical nerve stimulation (TENS) an interferential currents (IFC) in patients with nonspecific chronic low back pain: randomized controlled trial. Sao Paulo Med J 2011; 129(4):206-16.
15. Gundog M, Atamaz F, Kanyilmaz S et al. Interferential current therapy in patients with knee osteoarthritis. Am J Phys Med Rehabil 2011; Epub before print.
16. Kajbafzadeh AM, Sharifi-Rad L, Nejat F et al. Transcutaneous interferential electrical stimulation for management of neurogenic bowel dysfunction in children with myelomeningocele. Int J Colorectal Dis 2012; 27(4):453-8.
17. Clarke MC, Chase JW, Gibb S et al. Improvement of quality of life in children with slow transit constipation after treatment with transcutaneous electrical stimulation. J Pediatr Surg 2009; 44(6):1268-72; discussion 72.
18. Coban S, Akbal E, Koklu S et al. Clinical trial: transcutaneous interferential electrical stimulation in individuals with irritable bowel syndrome - a prospective double-blind randomized study. Digestion 2012; 86(2):86-93.

19. Koklu S, Koklu G, Ozguclu E et al. Clinical trial: interferential electric stimulation in functional dyspepsia patients - a prospective randomized study. Aliment Pharmacol Ther 2010; 31(9):961-8.
20. Food and Drug Administration. Warning letter. September 17, 1997. Available online at: http://www.fda.gov/downloads/ICECI/EnforcementActions/WarningLetters/1997/UCM065904.pdf
21. Blum K, Chen AL, Chen TJ et al. The H-Wave device is an effective and safe non-pharmacological analgesic for chronic pain: a meta-analysis. Adv Ther 2008; 25(7):644-57.
22. Kumar D, Marshall HJ. Diabetic peripheral neuropathy: amelioration of pain with transcutaneous electrostimulation. Diabetes Care 1997; 20(11):1702-5.
23. Kumar D, Alvaro MS, Julka IS et al. Diabetic peripheral neuropathy. Effectiveness of electrotherapy and amitriptyline for symptomatic relief. Diabetes Care 1998; 21(8):1322-5.
24. Julka IS, Alvaro M, Kumar D. Beneficial effects of electrical stimulation on neuropathic symptoms in diabetes patients. J Foot Ankle Surg 1998; 37(3):191-4.
25. Blum K, DiNubile NA, Tekten T et al. H-Wave, a nonpharmacologic alternative for the treatment of patients with chronic soft tissue inflammation and neuropathic pain: a preliminary statistical outcome study. Adv Ther 2006; 23(3):446-55.
26. Blum K, Chen TJ, Martinez-Pons M et al. The H-Wave small muscle fiber stimulator, a nonpharmacologic alternative for the treatment of chronic soft-tissue injury and neuropathic pain: an extended population observational study. Adv Ther 2006; 23(5):739-49.
27. Blum K, Chen AL, Chen TJ et al. Healing enhancement of chronic venous stasis ulcers utilizing H-WAVE® device therapy: a case series. Cases J 2010; 3:54.
28. Blum K, Chen AL, Chen TJ et al. Repetitive H-wave device stimulation and program induces significant increases in the range of motion of post-operative rotator cuff reconstruction in a double-blinded randomized placebo controlled human study. BMC Musculoskelet Disord 2009; 10:132.
29. Steinbok P, Reiner A, Kestle JR. Therapeutic electrical stimulation (ThresholdES) following selective posterior rhizotomy in children with spastic diplegic cerebral palsy: a randomized clinical trial. Dev Med Child Neurol 1997; 39(8):515-20.
30. Dali C, Hansen FJ, Pedersen SA et al. Threshold electrical stimulation (TES) in ambulant children with CP: a randomized double-blind placebo-controlled clinical trial. Dev Med Child Neurol 2002; 44(6):364-9.

31. van der Linden ML, Hazlewood ME, Aitchison AM et al. Electrical stimulation of gluteus maximus in children with cerebral palsy: effects on gait characteristics and muscle strength. Dev Med Child Neurol 2003; 45(6):385-90.
32. Fehlings DL, Kirsch S, McComas A et al. Evaluation of therapeutic electrical stimulation to improve muscle strength and function in children with types II/III spinal muscular atrophy. Dev Med Child Neurol 2002; 44(11):741-4.
33. Ozer K, Chesher SP, Scheker LR. Neuromuscular electrical stimulation and dynamic bracing for the management of upper-extremity spasticity in children with cerebral palsy. Dev Med Child Neurol. 2006; 48(7):559-63.
34. Kerr C, McDowell B, Cosgrove A et al. Electrical stimulation in cerebral palsy: a randomized controlled trial. Dev Med Child Neurol 2006; 48(11):870-6.
35. Lannin N, Scheinberg A, Clark K. AACPDM systematic review of the effectiveness of therapy for children with cerebral palsy after botulinum toxin A injections. Dev Med Child Neurol 2006; 48(6):533-9.
36. Chou R, Atlas SJ, Stanos SP, et al. Nonsurgical interventional therapies for low back pain: a review of the evidence for an American Pain Society clinical practice guideline. *Spine (Phila Pa 1976).* May 1 2009;34(10):1078-1093. PMID 19363456

Policy History

Original Effective Date: 02/01/2005
Current Effective Date: 01/08/2020

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.
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

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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
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.

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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.
Next Scheduled Review Date: 01/2021

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2019 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

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HCPCS	C1883, E0731, 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 the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated 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
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.

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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.

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