Electrical Stimulation for the Treatment of Muscle Rehabilitation, Pain and Miscellaneous Conditions

Medical Policy #: 01.01.23
Original Effective Date: November 2000
Reviewed: August 2022
Revised: August 2022

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DESCRIPTION

Electrical stimulation (ES) therapy involves the application of electrodes to the affected area of the body for the purpose of delivering electrical current. There are several forms of electrical current used in rehabilitation settings. Electrical stimulation is used for muscle re-education (disuse atrophy), pain relief, reduction of swelling and healing enhancement. However, electrical stimulation is also be used in the treatment of other conditions including insomnia, depression, anxiety, weight loss, and opioid withdrawal. Electrical stimulators may have controls for setting the pulse length, pulse repetition frequency, pulse amplitude, and triggering modes. Electrodes for such devices may be indwelling, implanted transcutaneously, or surface.

Clinical Content and Therapy Purpose

The purpose of using electrical stimulation is to provide treatment options that is an alternative to or an improvement on existing therapies.

Population
The population of interest is individuals with musculoskeletal conditions: muscle re-education (disuse atrophy), pain relief, reduction of swelling and healing enhancement.

The population of interest is individuals with insomnia, depression, anxiety, weight loss, and opioid withdrawal.

Interventions
Electrical stimulation for the treatment of muscle rehabilitation, pain and miscellaneous conditions.

Comparators
The purpose of using electrical stimulation is to provide treatment option that is an alternative to or an improvement on existing therapies.

Outcomes
The specific outcomes of interest are pain control, symptom management, increased functional capacity, and improved quality of life (QOL).

Neuromuscular and Functional Electrical Stimulation
Neuromuscular electrical stimulation (NMES) involves the use of a device which transmits an electrical impulse to the skin over selected muscle groups by way of electrodes. There are two broad categories of NMES. One type of device stimulates the muscle when the patient is in a resting state to treat muscle atrophy/disuse atrophy. The second type, also referred to as functional electrical stimulation is used to enhance functional activity of neurologically impaired patients. These electrical stimulators provide direct, alternating, pulsating and/or pulsed waveforms of energy. The devices are used to exercise muscles, demonstrate a muscular response to stimulation of a nerve and may have a combined unit that may include TENS to relieve pain.

Neuromuscular Muscular Electrical Stimulators (NMES)
Neuromuscular electrical stimulators (NMES) are small electronic devices that are affixed externally to the individual's skin by way of electrodes to provide direct stimulation of affected muscles. NMES stimulates muscle to maintain its tone during temporary extremity immobilization. The goal of NMES for an immobilized extremity following a documented injury or surgical intervention is to control edema, increase local blood circulation, maintain muscle tone or delay the development of disuse atrophy. NMES has also been proposed for other indications including treatment for muscle atrophy characteristic in conditions such as cerebral palsy, congestive heart failure and upper extremity hemiplegia (such as present with a stroke).

Examples of NMES include, but may not be limited to the following:

- **Biomove device** is an electromyography (EMG) triggered NMES used as a training system for rehabilitation of paralyzed muscles, mainly after stroke. This

device is designed to detect any EMG signals (nerve impulses from the brain to the muscles) that are to stimulate a muscle contraction but are to weak to do so. When the device detects these signals, it applies stimulation to the muscle and induces a contraction, to purportedly retrain the brain and muscle to properly coordinate contractions and movement. This device is also proposed for use for relaxation of muscle spasms and prevention or retardation of disuse atrophy.

- **Guardian Dysphagia Dule Chamber Unit and VitalStim Therapy** are devices proposed for use of muscle re-education by application of external stimulation for pharyngeal contraction.
- **RS-2m** muscle stimulator
- **RS-4i** sequential stimulator (also referred to as a combination unit) initially provides an interferential treatment (pain relief) followed by neuromuscular electrical stimulation (NMES) that reduces muscle spasms, increases circulation and prevents use atrophy.
- **RS-4m** muscle stimulator
- **The following are combination NMES and transcutaneous electrical stimulation (TENS) devices**
    - **Empi Phoenix** and conductive garment treats disuse atrophy by NMES and TENS can help manage patient's pain.
    - **Flex-MT Plus** provides neuromuscular electrical stimulation (NMES) to prevent muscle atrophy, for muscle re-education, to relax muscle spasms, to improve blood circulation, for postsurgical stimulation of calf muscles to prevent venous thrombosis, and/or to maintain or increase range of motion. I may provide biofeedback and/or transcutaneous electrical nerve stimulation (TENS) to treat pain.
    - **Kneehab XP** combines neuromuscular electrical stimulation (NMES) and transcutaneous electrical nerve stimulation (TENS) to improve knee stability during the first 90 days after surgery. Kneehab assists in regaining lost quadriceps strength.
    - **NexWave** combines interferential current (IFC) therapy for the purpose of pain relief, transcutaneous electrical stimulation (TENS) to provide better pain relief results and more intense therapeutic effect and neuromuscular electrical stimulation (NMES) to stimulate muscle contractions.
    - **QB1 System** assists patients overcome quad weakness by integrating next-generation muscle activation technology in a simple compressive wrap or post-operative brace. It uses an integrated, handheld controller to enable patients to treat muscle atrophy at home.

Summary of Evidence

Although the evidence is limited, neuromuscular electrical stimulation (NMES) for the treatment of disuse atrophy in individuals where the nerve supply to the muscle is intact and is supported by evidence for certain conditions to include the following:

- Previous immobilization of a joint or limb (arm or leg) by casting or splinting after a surgical intervention with failure to respond to or unable to participate in physical therapy

- Contractures due to scarring of soft tissue (e.g., burn scarring)
- Following total hip replacement surgery prior to initiation of physical therapy (until physical therapy begins)
- Following total knee replacement surgery with failure to respond to physical therapy.

However, for all other indications further controlled clinical trials are necessary to determine if the addition of NMES to the rehabilitative program will improve net health outcomes. The evidence is insufficient to determine the effects of the technology on net health outcomes.

Neuromuscular electrical stimulation (NMES) devices that incorporates muscular stimulation and interferential current stimulation modalities into one unit (e.g., RS-4i, RS-4m, RS-2s sequential stimulators) in the treatment of disuse atrophy or any other condition is considered investigational because its effectiveness has not yet been established in the peer-reviewed medical literature.

Functional Electrical Stimulators (FES)
Functional electrical stimulation (FES) is a type of neuromuscular stimulator the direct application of electric current to intact nerve fibers in a coordinated fashion to cause involuntary but purposeful contraction. FES bypasses the central nervous system and targets motor neurons innervating either skeletal muscle or other organ systems. Electrodes may be on the surface of the skin or may be surgically implanted along with the stimulator. FES is categorized as therapeutic and functional. Functional electrical stimulation attempts to prevent or reverse muscle atrophy and bone demineralization by stimulating paralyzed limbs to perform stationary exercise or assist with standing or walking. Functional electrical stimulation has also been investigated as a way to improve gait disorders of individuals with hemiplegia.

Examples of FES include, but may not be limited to the following:

Parastep System
The Parastep® Ambulation System works by delivering microcomputer-controlled electrical pulses through surface (skin) applied electrodes to nerves and muscles, causing muscle contractions. The computer is programmed to control the sequence of muscle contractions in the lower extremities that enable the functions of sit-to-stand, right and left step, and stand-to-sit. Users are taught to initiate functions by activating commands through switch modules mounted on the walker.

The system is designed to provide up to 6 channels of stimulation (i.e. stimulate up to 3 muscle groups on each leg/side). However, some individuals may require only 4 channels of stimulation to stand and ambulate.

- When 4 channels are used, electrical stimulation is directed to 4 electrodes on each lower extremity:

    - Stimulation of the quadriceps muscles results in knee extension, enabling the use to stand.
    - Stimulation of the peroneal nerve in the lower extremity initiates a triple-flexion reflex response, resulting in contraction of muscles to flex the hip, knee and ankle, which lifts the foot off the floor.
    - Subsequent quadriceps stimulation extends the knee in preparation for heel-strike and weight bearing.

- When 6 channels of stimulation are used, electrical stimulation is directed to the previously mentioned sites above and to two additional electrodes on the hip.
    - Stimulation of gluteal muscles extends the hips, contributing to stability while standing and taking steps.

The user initiates and controls the intensity of stimulation to the muscles and nerves through the keypad on the stimulator/control unit or through two switch modules mounted on the walker handle bars. The walker provides balance and stability during standing and walking.

Physical therapy is a key component to the Parastep® Ambulation System. Thirty-two sessions of physical therapy including instruction on system use and gait training, are provided to users when they purchase a system. The training is provided by hospital based physical therapists who have completed Sigmedics, Inc.'s clinical training program.

Each user's progress is carefully monitored with frequent adjustments made in the training program to accommodate each user's individual requirements. Treatment sessions progress at a pace set by each user's ability, skill and proficiency.

To acquire a Parastep® Ambulation System an individual must participate in an approved Parastep® clinical training program and obtain a physician's prescription.

Other FES Devices

- ERGYS (leg cycle ergometer), REGYS (leg cycle ergometer), RT200 Elliptical, RT300 RES cycle ergometer (also referred to as FES bicycle), StimMaster Galaxy (FES exercise bike) or the RT600 Step and Stand Rehabilitation Therapy System for stationary exercise to prevent or reduce muscle atrophy in upper and lower extremities in individuals with hemiplegia or quadriplegia.
- The FES Cycle Therapy System (RT300) is described as a neuromuscular electrical stimulation device to reduce spasticity or facilitate voluntary motor control in individuals with spinal cord injury.
- NESS H200 Handmaster NMS1 system used for upper limb paralysis or hemiplegia.
- NESS L300 Foot Drop System or NESS L300 Plus System used for foot drop in children and adults, as a result of cerebral palsy (CP), multiple sclerosis (MS), traumatic brain injury (TBI), stroke (CVA) or an incomplete spinal cord injury;

- Walkaide or ODFS Dropped Foot Stimulator used for foot drop as a result of cerebral palsy (CP), multiple sclerosis (MS), traumatic brain injury (TBI), stroke (CVA), or an incomplete spinal cord injury.
- MyndMove is a functional electrical stimulation (FES) device intended to improve voluntary hand and arm movement in patients with paralysis after a stroke or spinal cord injury. The system comprises an eight-channel electrical stimulator, a touch-screen interface, and embedded stimulation protocols. Electrical stimulation, in conjunction with patients' motion attempts, is intended to aid recovery by promoting the formation of new motor neural pathways.

Summary of Evidence
Functional electrical stimulation (FES) has been proposed for reduce muscle atrophy is upper and lower extremities, improving ambulation in individuals with gait disorders such as drop foot, hemiplegia due to stroke, cerebral injury, or incomplete SCI. Randomized controlled trials (RCTs) and case series have primarily included small patient populations with short-term follow-ups. FES devices discussed in this medical policy except Parastep system are considered home exercise equipment (non-medical self-care and/or self-help training) and are generally excluded from coverage regardless of the indication they are being prescribed and considered not medically necessary.

The Parastep system is a functional electrical stimulation device to provide individuals with spinal cord injury (SCI) the ability to stand or walk. No controlled trials were identified on FES for standing and walking in patients with SCI. The evidence is limited and consists of case series. Case series are considered adequate for this condition because there is no chance for ambulation in patients with SCI between segments T4 to T12. As stated by various authors, these systems are not designed as alternatives to a wheelchair and offer, at best, limited, short-term ambulation. Some studies have reported improvements in intermediate outcomes, but improvement in health outcomes (e.g., ability to perform ADLs) have not been demonstrated. Finally, evaluations of these devices were performed immediately after initial training or during limited study period durations. There are no data in which patients remained compliant and committed with long-term use. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Miscellaneous Electrical Stimulation Devices

Bioelectric Therapy
Bioelectric therapy is used to treat chronic pain and acute pain conditions. Using bioelectric currents, bioelectrical therapy relieves pain by interrupting pain signals before they reach the brain. Bioelectric therapy also prompts the body to produce endorphins which help relieve pain. Bioelectric therapy should be used as part of a total pain management program and may reduce the dose of some pain medications by up to 50%. During bioelectrical therapy electrodes are hooked up to a computer program that provides high frequency alternating electrical currents and during the treatment the response to electrical stimulation is measured. Therapy usually begins with five sessions

in one week, followed by three treatments per week. A normal course of treatment includes 16 to 20 treatments.

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

Cranial Electrostimulation/Auricular Electrostimulation
Cranial electrotherapy stimulation (CES), also known as cranial electrical stimulation, transcranial electrical stimulation, or electrical stimulation therapy, delivers weak pulses of electrical current to the earlobes, mastoid processes, or scalp with devices such as the Alpha-Stim. Auricular electrostimulation involves stimulation of acupuncture points on the ear. Devices, including the P-Stim and E-pulse, provide ambulatory auricular electrical stimulation over a period of several days. CES is being evaluated for a variety of conditions, including pain, insomnia, depression, anxiety, and functional constipation. Auricular electrical stimulation is being evaluated for pain, weight loss, and opioid withdrawal.

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Interest in CES began in the early 1900s on the theory that weak pulses of electrical current have a calming effect on the central nervous system. The technique was further developed in the U.S.S.R. and Eastern Europe in the 1950s as a treatment for anxiety and depression and use of CES later spread to Western Europe and the United States as a treatment for various psychological and physiological conditions. Presently, the mechanism of action is thought to be the modulation of activity in brain networks by direct action in the hypothalamus, limbic system, and/or the reticular activating system. One device used in the United States is the Alpha-Stim CES, which provides pulsed, low-intensity current via clip electrodes that attach to the earlobes. Other devices place the electrodes on the eyelids, frontal scalp, mastoid processes, or behind the ears. Treatments may be administered once or twice daily for several days to several weeks.

Other devices provide electrical stimulation to auricular acupuncture sites over several days. One device, the P-Stim, is a single-use miniature electrical stimulator for auricular acupuncture points that is worn behind the ear with a self-adhesive electrode patch. A selection stylus that measures electrical resistance is used to identify 3 auricular acupuncture points. The P-Stim device connects to 3 inserted acupuncture needles with caps and wires. The device is preprogrammed to be on for 180 minutes, then off for 180 minutes. The maximum battery life of this single-use device is 96 hours.

Electrical and Electromagnetic Stimulation for the Treatment of Arthritis
Pulsed electrical and electromagnetic stimulation are being investigated to improve functional status and relieve pain related to osteoarthritis and rheumatoid arthritis that is unresponsive to other standard therapies. Electrical stimulation is provided using a device that noninvasively delivers a subsensory, low-voltage, monophasic electrical field to the target site of pain. Pulsed electromagnetic fields are delivered using coils placed over the skin. In basic research studies, pulsed electrical stimulation has been shown to alter chondrocyte-related gene expression in vitro and to have regenerative effects in animal models of cartilage injury. It is proposed that the device treats the underlying cause of the disease by stimulating the joint tissue and improving the overall health of the joint and that it provides a slow-acting, but longer-lasting improvement in symptoms. Therefore, pulsed electrical stimulation is proposed to be similar to bone stimulator therapy for fracture nonunion.

Devices include the following:

- BioniCare Bio-1000™ stimulator (VQ OrthoCare): Delivers pulsed electrical stimulation for adjunctive treatment of osteoarthritis of the knee, and rheumatoid arthritis of the hand.
- OrthoCor™ Active Knee System (OrthoCor Medical; acquired by Caerus Corp. in 2016): Uses pulsed electromagnetic field energy at a radiofrequency of 27.12 MHz to treat pain. It is indicated for adjunctive use in the palliative treatment of postoperative pain and edema in superficial soft tissue and for the treatment of muscle and joint aches and pain associated with overexertion, strains, sprains, and arthritis.
- SofPulse™ (also called Torino II, 912-M10, and Roma3™; Ivivi Health Sciences, renamed Amp Orthopedics): A short-wave diathermy device that applies electromagnetic energy at a radiofrequency of 27.12 MHz (K070541). The device is indicated for adjunctive use in the palliative treatment of postoperative pain and edema in superficial soft tissue.
- Palermo device (Ivivi Health Sciences): Is a portable battery-operated device.
- ActiPatch® (BioElectronics): Nonprescription use for adjunctive treatment of plantar fasciitis of the heel and osteoarthritis of the knee.

Electro Therapeutic Point Stimulation Therapy (ETPS)
Electro therapeutic point stimulation therapy (ETPS) combines the following:

- Electrical nerve stimulation
- Acupuncture

- Muscle relaxation
- Nerve stimulation

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

Frequency – Specific Microcurrent (FSM)
Frequency – specific microcurrent (FSM) is a way to relieve pain using very low levels of electrical current. Various frequencies can be used to potentially reduce swelling (inflammation), repair tissue and reduce pain. One of the ways FSM works is by potentially increasing the production of a substance called ATP that's inside injured tissues. ATP is the major source of energy for all cellular reactions in the body. Because treatment with FSM can increase the amount of ATP that's created in damaged cells by as much as 500%, this treatment may help with recovery. Depending on the condition, treatment with FSM can "loosen" or soften the muscles, which can help relieve pain or stiffness.

High Frequency Impulse Therapy (HIFT)
High frequency impulse therapy (HIFT) is a recently developed treatment for chronic pain, which purportedly mimics a frequency wave similar to that of implanted neuromodulation devices (i.e., some spinal cord stimulators). The stimulation is delivered via electrodes, applied to the skin, which are directly attached to the stimulator (without the need for lead wires). An example of this device includes, but may not be limited to, the ENSO Device.

H-WAVE Electrical Stimulation
H-WAVE electrical stimulation electrical stimulation device generates a biphasic, exponentially decaying waveform with pulse wide widths. Its waveform distinguishes it from TENS and other forms of electrical stimulators. H-WAVE is classified as a powered muscle stimulator. The hypothesis that the H-WAVE device (Electronic Waveform Lab, Inc., Huntington Beach, CA), a small-diameter fiber stimulator, is a paradigm shift of electrotherapeutic treatment of pain associated with human neuropathies and sports injuries is based on a number of its properties. The primary effect of H-WAVE device stimulation (HWDS) is the stimulation of "red-slow-twitch" skeletal muscle fibers. It is proposed, based on the unique waveform, that the H-WAVE device specifically and directly stimulates the small smooth muscle fibers within the lymphatic vessels ultimately leading to fluid shifts and reduced edema. The H-WAVE device was designed to stimulate an ultra-low frequency (1-2 Hz), low tension, non-tetanizing, and nonfatiguing contraction, which closely mimics voluntary or natural muscle contractions. The H-WAVE device can stimulate small fibers due in part to its exponentially decaying

waveform and constant current generator activity. The main advantage of these technologies over currently applied electrical stimulators (e.g., TENS, interferential, NMES high-volt galvanic, etc.) is that H-WAVE small fiber contraction does not trigger an activation of the motor nerves of the large white muscle fibers or the sensory delta and C pain nerve fibers, thus eliminating the negative and painful effects of tetanizing fatigue, which reduces transcapillary fluid shifts. Another proposed function of the H-WAVE device is an anesthetic effect on pain conditions, unlike a TENS unit which in the short term activates a hypersensory overload effect (gate theory) to stop pain signals from reaching the thalamic region of the brain. When the H-WAVE device is used at high frequency (60 Hz), it supposedly acts intrinsically on the nerve to deactivate the sodium pump within the nerve fiber, leading to a long-lasting anesthetic/analgesic effect due to an accumulative postsynaptic depression. The large pulse width theoretically enables contraction in the muscle for extended periods of time at a low fatigue rate and increases circulation, muscle relaxation, pain relief and wound healing. H-WAVE stimulation has been used in the treatment of pain related to a variety of etiologies, such as diabetic neuropathy, muscle sprains, temporomandibular joint dysfunctions, or reflex sympathetic dystrophy. HWAVE electrical stimulation must be distinguished from the H-waves that are a component of electromyography.

Interferential Therapy (IFT)/Interferential Current Therapy (ICT)
Interferential therapy (IFT) is a treatment modality that is proposed to relieve musculoskeletal pain and increase healing in soft tissue injuries and bone fractures. Two medium-frequency, pulsed currents are delivered via electrodes placed on the skin over the targeted area producing a low-frequency current. IFT delivers a crisscross current resulting in deeper muscle penetration. It is theorized that IFT prompts the body to secrete endorphins and other natural painkillers and stimulates parasympathetic nerve fibers to increase blood flow and reduce edema.

Microcurrent Electrical Nerve Stimulation (MENS)
MENS involves the use of a device that delivers small amounts of electrical current (millionths of an amp) to help relieve pain and heal soft tissues of the body. The application of microcurrent stimulation to an injured area is proposed to realign the body's electrical current and increase the production of adenosine triphosphate, resulting in increased healing and recovery and blocking of perceived pain. The electrical current is subsensory and usually not felt.

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

Another example of PENFS is the Morph Device which has received FDA approval for the treatment of pain associated with opioid withdrawal; it is similar to the IBStim device, but only targets the nerve branches of cranial nerves V, VII, IX and X; it is left in place for up to 10 days.

Threshold Electrical Stimulation
Threshold electrical stimulation 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.

Transcutaneous Electrical Modulation Pain Reprocessing (e.g., Scrambler Therapy, TEMPR therapy)
Transcutaneous electrical modulation pain reprocessing (TEMPR), also called Scrambler therapy or Calmare® pain therapy (Calmare Therapeutics), delivers electrical stimulation via the nerve fibers to convey a message of normality to the central nervous system (CNS) by a procedure defined as "scrambling" or "tricking" of information. The device is proposed to send a very low current of electrical stimulation through the nerve fibers, which carries a "no pain" signal to the brain that overrides the previous pain signal.

Summary of Evidence
Based on the review of the peer reviewed medical literature the evidence is currently insufficient to conclude that the use of these miscellaneous stimulation devices above for muscle re-education (disuse atrophy), pain relief, reduction of swelling and healing enhancement are effective compared with usual care dependent on the condition being treated. Further long-term randomized controlled trials (RCTs) with follow-up assessments are needed. The evidence is insufficient to determine the effects of the technology on net health outcomes

Based on the review of the peer reviewed medical literature individuals with psychiatric, behavioral, neurological conditions (e.g., depression, anxiety, Parkinson disease, addiction) the evidence is currently insufficient to conclude that the use of these miscellaneous stimulation devices above provides reduction in symptoms and improved functional outcomes compared with usual care dependent on the condition being treated. Further long-term randomized controlled trials (RCTs) with follow-up assessments are needed. The evidence is insufficient to determine the effects of the technology on net health outcomes.

Regulatory Status

A variety of functional electrical stimulation (FES) devices have been cleared by the U.S. Food and Drug Administration (FDA) and are available for home use. Table below provides examples of devices designed to improve hand and foot function as well as cycle ergometers for home exercise:

Device	Manufacturer	Device Type
Freehand®	No longer manufactured	Hand stimulator
NESS H200® (previously Handmaster)	Bioness	Hand stimulator
MyndMove System	MyndTec	Hand stimulator
ReGrasp	Rehabtronics	Hand stimulator
WalkAide® System	Innovative Neurotronics (formerly NeuroMotion)	Foot drop stimulator
ODFS® (Odstock Dropped Foot Stimulator)	Odstock Medical	Foot drop stimulator
ODFS® Pace XL	Odstock Medical	Foot drop stimulator
L300 Go	Bioness	Foot drop stimulator
L100 Go	Bioness	Foot drop stimulator
Foot Drop System	SHENZHEN XFT Medical	Foot drop stimulator
Nerve And Muscle Stimulator	SHENZHEN XFT Medical	Foot drop stimulator
MyGait® Stimulation System	Otto Bock HealthCare	Foot drop stimulator
ERGYS (TTI Rehabilitation Gym)	Therapeutic Alliances	Leg cycle ergometer
RT300	Restorative Therapies, Inc (RTI)	Cycle ergometer
Myocycle Home	Myolyn	Cycle ergometer
StimMaster Orion	Electrologic (no longer in business)	

To date, the Parastep® Ambulation System is the only noninvasive functional walking neuromuscular stimulation device to receive PMA from FDA. The Parastep device is approved to "enable appropriately selected skeletally mature spinal cord injured patients (level C6-T12) to stand and attain limited ambulation and/or take steps, with assistance if required, following a prescribed period of physical therapy training in conjunction with rehabilitation management of spinal cord injury."

A variety of neuromuscular electrical stimulation (NMES) for muscle rehabilitative devices have been cleared by the U.S. Food and Drug Administration (FDA) and are available for home use.

Microcurrent electrical nerve stimulation therapy (MENS) devices are categorized as TENS devices intended for pain relief. They are regulated by the FDAs' premarket approval (PMA) process.

Transcutaneous Electrical Modulation Pain Reprocessing e.g., scrambler therapy (ST) was initially approved by the U.S. Food and Drug Administration (FDA) February 2009. A second 510(k) clearance was issued May 2015 for the STMC-5A Device.

The BioniCare Bio-1000™ stimulator (VQ OrthoCare) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process in 1997 to deliver pulsed electrical stimulation for adjunctive treatment of osteoarthritis of the knee, then later for rheumatoid arthritis of the hand.

The OrthoCor™ Active Knee System (OrthoCor Medical; acquired by Caerus Corp. in 2016) uses pulsed electromagnetic field energy at a radiofrequency of 27.12 MHz to treat pain. In 2009, the OrthoCor Knee System was cleared for marketing by the FDA through the 510(k) process and is classified as a short-wave diathermy device for use other than applying therapeutic deep heat (K091996, K092044). The predicate devices are the OrthoCor (K091640) and Ivivi Torino II™ (K070541). FDA product code: ILX.

In 2008, the SofPulse™ (also called Torino II, 912-M10, and Roma3™; Ivivi Health Sciences, renamed Amp Orthopedics) was cleared for marketing by the FDA through the 510(k) process as a short-wave diathermy device that applies electromagnetic energy at a radiofrequency of 27.12 MHz (K070541). The Palermo device (Ivivi Health Sciences) is a portable battery-operated device. FDA product code: ILX.

In 2017, the ActiPatch® (BioElectronics) was cleared for marketing by the FDA through the 510(k) process for nonprescription use for adjunctive treatment of plantar fasciitis of the heel and osteoarthritis of the knee. FDA product code: PQY.

A number of IFT 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). IFT may be included in multimodal electrotherapy devices such as transcutaneous electrical nerve stimulation and functional electrostimulation.

A number of devices for cranial electrotherapy stimulation (CES) have been cleared by the U.S. Food and Drug Administration (FDA) through the 510(k) process. In 1992, the Alpha-Stim® CES device (Electromedical Products International) received marketing clearance for the treatment of anxiety, insomnia, and depression. Devices cleared since 2000 are summarized in the below table:

Device Name	Manufacturer	Date Cleared	Indications
Cervella	Innovative Neurological Devices	03/07/2019	Insomnia, depression, anxiety
Cranial Electrical Nerve Stimulator	Johari Digital Healthcare	05/29/2009	Insomnia, depression, anxiety

Elexoma Medic™	Redplane AG	05/21/2008	Insomnia, depression, anxiety
CES Ultra™	Neuro-Fitness	04/05/2007	Insomnia, depression, anxiety
Net-2000 Microcurrent Stimulator	Auri-Stim Medical	10/13/2006	Insomnia, depression, anxiety
Transcranial Electrotherapy Stimulator-A, Model TESA-1	Kalaco Scientific	07/21/2003	Insomnia, depression, anxiety

Several devices for electroacupuncture designed to stimulate auricular acupuncture points have been cleared for marketing by the FDA through the 510(k) process. Devices cleared since 2000 are summarized in table below:

Device Name	**Manufacturer**	**Date Cleared**	**Indication**
Drug Relief	DyAnsys Inc	05/02/2018	Reduce symptoms of opioid withdrawal
Ansistem-Pp	DyAnsys Inc	03/09/2017	Practice of acupuncture by qualified practitioners of acupuncture as determined by the states
NSS-2 Bridge	Innovative Health Solutions	2017	Substance use disorders
Stivax System	Biegler Gmbh	05/26/2016	Practice of acupuncture by qualified practitioners as determined by the states
ANSiStim®	DyAnsys Inc	05/15/2015	Practice of acupuncture by qualified practitioners as determined by the states
Pantheon Electrostimulator	Pantheon Research	11/07/2014	Practice of acupuncture by qualified practitioners as determined by the states
Electro Auricular Device	Navigant Consulting, Inc.	10/02/2014	Practice of acupuncture by qualified practitioners as determined by the states
P-Stim	Biegler GMBH	06/27/2014	Practice of acupuncture by qualified practitioners as determined by the states
Jiajian Cmn Stimulator	Wuxi Jiajian Medical Instrument Co., Ltd.	08/16/2013	Practice of acupuncture by qualified practitioners as determined by the states

JiaJian Electro-Acupuncture Stimulators	Wuxi Jiajian Medical Instrument Co., Ltd.	04/11/2013	Practice of acupuncture by qualified practitioners as determined by the states
Multi-Purpose Health Device	UPC Medical Supplies, Inc. DBA United Pacific Co.	08/05/2010	Unknown - Summary not provided
Electro-Acupuncture: Aculife/Model ADOC-01	Inno-Health Technology, Inc.	04/02/2010	Practice of acupuncture by qualified practitioners as determined by the states
e-Pulse®	Medevice Corporation	12/07/2009	Practice of acupuncture by qualified practitioners as determined by the states
Model ES-130	Ito Co., Ltd.	11/24/2008	Practice of acupuncture by qualified practitioners as determined by the states
P-Stim™	Neuroscience Therapy Corp.	03/30/2006	Practice of acupuncture by qualified practitioners as determined by the states
Aculife	Inno-Health Technology, Inc.	03/28/2006	Practice of acupuncture by qualified practitioners as determined by the states
AcuStim	S.H.P. Intl. Pty., Ltd.	06/12/2002	As an electroacupuncture device

[a] "FDA cleared the NSS-2 Bridge Device for Substance Use Disorders through the de novo premarket review pathway, a regulatory pathway for some low- to moderate-risk devices that are novel and for which there is no legally marketed predicate device to which the device can claim substantial equivalence"
N/A: Not applicable

Food and Drug Administration approved the IB-Stim Stimulator June 2019 to aid in the reduction of functional abdominal pain in individuals 11-18 years of age with irritable bowel syndrome (IBS). The IB-Stim is a prescription-only device comprised of a small single-use electrical nerve stimulator that is placed behind the patient's ear. It contains a battery-powered chip that emits low-frequency electrical pulses to stimulate branches of certain cranial nerves continuously for five days, at which time it is replaced. Stimulating nerve bundles in and around the ear is thought to provide pain relief. Patients can use the device for up to three consecutive weeks to reduce functional abdominal pain associated with IBS.

PRIOR APPROVAL

Not applicable.

POLICY

Neuromuscular Electrical Stimulation (NMES) (E0745)

Neuromuscular Electrical Stimulation (NMES) (e.g., RS-2m muscle stimulator or RS-4m muscle stimulator) may be considered **medically necessary** when prescribed by the treating physician for the treatment of disuse atrophy (muscle atrophy/wasting) in the setting of intact nerve supply (including brain, spinal cord and peripheral nerves) to the muscle resulting from one of the following conditions:

- Previous immobilization of a joint or limb (arm or leg) by casting or splinting after a surgical intervention with failure to respond to or unable to participate in physical therapy; **or**
- Contractures due to scarring of soft tissue (e.g., burn scarring); **or**
- Following total hip replacement surgery prior to initiation of physical therapy (until physical therapy begins); **or**
- Following total knee replacement surgery with failure to respond to physical therapy.

Neuromuscular Electrical Stimulation (NMES) is considered **investigational** when the above criteria are not met and for all other indications, including but not limited to the following because the evidence is insufficient to determine the effects of the technology on net health outcomes:

- Prevent disuse atrophy/muscle atrophy
- For the treatment of denervated muscles
- For the treatment of hip or knee osteoarthritis
- Reduce lymphedema
- Reduce post-surgical swelling
- As a technique to increase circulation
- Following ACL/MCL repair
- Treatment of pain for various musculoskeletal conditions
    - Low back pain
    - Patellofemoral syndrome
    - Spinal stenosis
    - Muscle strains/sprains
    - Scoliosis
- Cerebral palsy
- Cerebral vascular accident
- Chronic obstructive pulmonary disease (COPD)
- Dysphagia

The following neuromuscular electrical stimulation (NMES) devices are considered **investigational** for all indications because the evidence is insufficient to determine the effects of the technology on net health outcomes:

- Guardian Dysphagia Dule Chamber Unit or VitalSTim Therapy
- Combination or sequential units to include interferential therapy (IFT) or TENS
    - Empi Phoenix
    - Flex-MT Plus
    - Kneehab XP
    - NexWave
    - QB1
    - RS-4i devices
- Biomove Device (EMG triggered NMES)

Functional Electrical Stimulation (FES)

ParaStep® Ambulation System (E0764)
Functional electrical stimulation (FES) devices for exercise in individuals with spinal cord injury (e.g., Parastep® Ambulation System) is considered **investigational** because the evidence is insufficient to determine the technology results in an improvement in the net health outcomes.

Other Functional Electrical Stimulation (FES) Devices
Functional electrical stimulation (FES) devices (E0770, E1399) including but not limited to the following are considered **not medically necessary** as they are considered home exercise equipment (non-medical self-care and/or self-help training) and are generally excluded from coverage regardless of the indication they are being prescribed for to include the treatment of disuse atrophy (muscle atrophy/wasting):

- ERGYS (leg cycle ergometer)
- REGYS (leg cycle ergometer)
- RT200 Elliptical
- RT300 RES cycle ergometer (also referred to as FES bicycle)
- StimMaster Galaxy (FES exercise bike)
- RT600 Step and Stand Rehabilitation Therapy System for stationary exercise
- FES Cycle Therapy System (RT300)
- Walkaide or ODFS Dropped Foot Stimulation
- Myndmove
- NESS H200 Handmaster
- Ness L300 Foot Drop System or NES L300 Plus System

Miscellaneous Electrical Stimulation Devices
The following electrical stimulation device are considered **investigational** for all indications because the evidence is insufficient to determine the effects of the technology on net health outcomes:

- Auricular electric stimulation

- Bioelectric nerve block (electroceutical therapy)
- Cefaly/Cefaly supraorbital transcutaneous neurostimulation
- Cranial electrostimulation
- Electro therapeutic point stimulation (ETPSSM)
- Frequency-specific microcurrent (FSM)
- High frequency impulse therapy (ENSO Device)
- H-WAVE electrical stimulation
- Interferential therapy (IFT)/Interferential current stimulation (ICT)
- Microcurrent Electrical Nerve Stimulation (MENS)
    - Algonix
    - Alpha-Stim M
    - Electro-Myopulse 75L
    - MICROCURRENT
    - Myopulse
- Percutaneous electrical field stimulation (PENFS)
    - IB-Stim Stimulator
    - Morph Device (NSS-2 Bridge Device)
- Threshold electrical stimulation
- Transcutaneous Electrical Stimulation (scrambler therapy) (0278T)

Pulsed electrical and electromagnetic stimulation (E0762) is considered **investigational** for the treatment of osteoarthritis and rheumatoid arthritis including but not limited to the following because the evidence is insufficient to determine the effects of the technology on net health outcomes:

- BioniCare Bio-1000 stimulator
- OrthoCor Active Knee System
- SofPulse (also called Torino II, 912-M10, and Roma3)
- Palermo device
- ActiPatch

Policy Guidelines

The American Spinal Injury Association (ASIA) Impairment Scale is a classification system used to describe the extent of spinal cord injury (SCI).

The ASIA Impairment Scale:
A.Complete: No motor or sensory function is preserved in the sacral segments S4 – S5

B. Incomplete: Sensory but not motor function is preserved below the neurological level and includes the sacral segments S4 – S5

C. Incomplete: Motor function is preserved below the neurological level, and more than half of key muscles below the neurological level have a muscle grade less than 3

D. Incomplete: Motor function is preserved below the neurological level, and at least half of key muscles below the neurological level have a muscle grade of 3 or more

E. Normal: Motor and sensory function are normal

PROCEDURE CODES AND BILLING GUIDELINES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- 0278T Transcutaneous electrical modulation pain reprocessing (e.g., Scrambler Therapy), each treatment session (includes placement of electrodes)
- 0720T Percutaneous electrical nerve field stimulation, cranial nerves, without implantation
- 0766T Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, initial treatment, with identification and marking of the treatment location, including noninvasive electroneurographic localization (nerve conduction localization), when performed; first nerve
- 0767T Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, initial treatment, with identification and marking of the treatment location, including noninvasive electroneurographic localization (nerve conduction localization), when performed; each additional nerve (List separately in addition to code for primary procedure)
- 0768T Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, subsequent treatment, including noninvasive electroneurographic localization (nerve conduction localization), when performed; first nerve
- 0769T Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, subsequent treatment, including noninvasive electroneurographic localization (nerve conduction localization), when performed; each additional nerve (List separately in addition to code for primary procedure)
- 0783T Transcutaneous auricular neurostimulation, set-up, calibration, and patient education on use of equipment
- A4596 Cranial electrotherapy stimulation (ces) system supplies and accessories, per month
- E0744 Neuromuscular stimulator for scoliosis
- E0745 Neuromuscular stimulator, electronic shock unit
- E0762 Transcutaneous electrical joint stimulation device system, includes all accessories
- E0764 Functional neuromuscular stimulation, transcutaneous stimulation of sequential muscle groups of ambulation with computer control, used for walking by spinal cord injured, entire system, after completion of training program.

- E0770 Functional electrical stimulator, transcutaneous stimulation of nerve and/or muscle groups, any type, complete system, not otherwise specified.
- E1399 Miscellaneous durable medical equipment
- K1002 Cranial electrotherapy stimulation (CES) system, includes all supplies and accessories, any type
- S8130 Interferential current stimulator, 2 channel
- S8131 Interferential current stimulator, 4 channel
- S8930 Electrical stimulation of auricular acupuncture points; each 15 minutes of personal one-on-one contact with patient

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POLICY HISTORY		
Date	**Reason**	**Action**
August 2022	Annual Review	Policy Revised
December 2021	Interim Review	Policy Revised
August 2021	Annual Review	Policy Revised
July 2020	Annual Review	Policy Revised
July 2019	Annual Review	Policy Revised
August 2018	Annual Review	Policy Revised
August 2017	Annual Review	Policy Revised
August 2016	Annual Review	Policy Revised
September 2015	Annual Review	Policy Revised
November 2014	Annual Review	Policy Revised
January 2014	Annual Review	Policy Revised and New Policy Created
January 2013	Annual Review	Policy Renewed
January 2012	Annual Review	Policy Renewed
February 2011	Interim Review	Policy Revised
October 2010	Annual Review	Policy Renewed

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

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