Introduction

When muscles can't be used after an injury or surgery, there's a risk that the tissue will deteriorate or waste away. This is known as disuse atrophy. Neuromuscular electrical stimulation (NMES) is a way to keep muscles active so they won't atrophy. In NMES, an electrode — a patch attached to skin that can transmit electrical signals into the body — is placed over the muscles to be stimulated. A device then sends an electrical signal to the electrode and through the skin. The muscle contracts. This contraction keeps the muscles active when they otherwise wouldn't be. This policy describes when NMES may be considered medically necessary. Other types of electrical stimulation have been proposed to try to improve function or relieve pain. These are considered investigational (unproven). There's not enough evidence to show they are effective.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can
be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

## Policy Coverage Criteria

<table>
<thead>
<tr>
<th>Service</th>
<th>Medical Necessity</th>
</tr>
</thead>
</table>
| Services eligible for reimbursement | Use of a neuromuscular electrical stimulator (NMES) via an open loop system, including but not limited to the RS 4m and RS 2m, may be considered medically necessary for disuse atrophy when the nerve supply to the muscle is intact and the patient has any of the following non-neurological causes for disuse atrophy:  
  - Previous casting or splinting of a limb (arm or leg)  
  - Contractures due to soft tissue scarring from burns  
  - Previous major knee surgery (eg, total knee replacement), when there is a failure to respond to physical therapy  
  - Recent hip replacement surgery (up until the time physical therapy begins) |

A conductive garment may be needed when a member meets criteria for treatment with a neuromuscular electrical stimulation device (NMES) and has one of the following medical indications:  
  - The treatment site is large and using a large number of standard electrodes is impractical  
  - There are multiple large treatment sites on the body that make using standard electrodes impractical  
  - The treatment site is hard to reach using standard electrodes and lead wires  
  - The member has a skin sensitivity that precludes use of standard electrodes, adhesive tape or lead wires |

Note: Functional neuromuscular electrical stimulators (closed loop systems) are addressed in a separate policy (see Related Medical Policies).
<table>
<thead>
<tr>
<th>Service</th>
<th>Investigational</th>
</tr>
</thead>
</table>
| Services not eligible for reimbursement | Neuromuscular electrical stimulators (NMES) are considered investigational when used for ANY of the following unproven indications:  
  - General muscle strengthening in healthy individuals  
  - Cardiac conditioning  
  - Treatment of denervated muscles  
  - Treatment of idiopathic scoliosis  
  
  Electrical sympathetic stimulation therapy devices are considered investigational.  
  
  Galvanic or high-voltage galvanic stimulation is considered investigational in the treatment of chronic pain (eg, FastStart HVPC).  
  
  H-wave stimulation is considered investigational. Microcurrent electrical nerve stimulation (MENS) devices are considered investigational (eg, Algonix, Alpha Stim M, ClearUP™ Sinus Pain Relief, MENS 2000, MICROCURRENT, Myopulse, Electro-Myopulse 75L).  
  
  Pulsed electrical stimulation and pulsed electromagnetic therapy are considered investigational for any indication including, but not limited to the treatment of osteoarthritis, rheumatoid arthritis, neuropathic pain (eg, diabetic peripheral neuropathy), post-operative or non-post-operative pain, or to treat wounds. (HCPCS E0762).  
  
  Transcutaneous electrical modulation pain reprocessing (TEMPR) (also called Scrambler therapy or Calmare® pain therapy) is considered investigational (CPT 0278T).  
  
  Transcutaneous supraorbital electrical nerve stimulator (Cefaly) is considered investigational for the prevention and treatment of migraine headaches and all other indications. |
Documentation Requirements

The patient’s medical records submitted for review should document that medical necessity criteria are met. The record should include the following:

- For neuromuscular electrical stimulator (NMES):
  - Clinical documentation showing that member has disuse atrophy (loss/decrease of muscle mass due to lack of use) where the nerve supply to the muscle is intact and the member has any of the following non-neurological reasons for disuse atrophy:
    - Previous casting or splinting of a limb
    - Contractures due to burn scarring or recent hip replacement surgery (up until the time physical therapy begins)
    - Previous major knee surgery when there is a failure to respond to physical therapy

- For a conductive garment clinical documentation of all of the above plus documentation of one of the following medical reasons:
  - The treatment site is large and using a large number of standard electrodes is impractical
  - There are multiple large treatment sites on the body that make using standard electrodes impractical
  - The treatment site is hard to reach using standard electrodes and lead wires
  - The member has a skin sensitivity that precludes use of standard electrodes, adhesive tape, or lead wires

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td><strong>CPT</strong></td>
<td>Transcutaneous electrical modulation pain reprocessing (eg, scrambler therapy), each treatment session (includes placement of electrodes)</td>
</tr>
<tr>
<td><strong>HCPCS</strong></td>
<td>Neuromuscular stimulator, electronic shock unit</td>
</tr>
<tr>
<td>E0745</td>
<td>Nonthermal pulsed high frequency radiowaves, high peak power electromagnetic energy treatment device</td>
</tr>
<tr>
<td>E0761</td>
<td>Transcutaneous electrical joint stimulation device system, includes all accessories</td>
</tr>
<tr>
<td>E1399</td>
<td>Durable medical equipment, miscellaneous (Determine if an alternative HCPCS Level II or a CPT code better describes the service being reported. This code should be used only if a more specific code is unavailable.)</td>
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<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>L8679</td>
<td>Implantable neurostimulator, pulse generator, any type</td>
</tr>
</tbody>
</table>

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

### Related Information

### Definition of Terms

**Conductive garment:** A form-fitted garment with integrated conductive fibers that are separated from the patient's skin by a layer of fabric.

**Disuse atrophy:** Gradual wasting or deterioration of a muscle when not used or subjected to prolonged inactivity, such as when an arm is in a cast for a long time (see muscle atrophy).

**Muscle atrophy:** Muscle wasting or tissue loss that occurs when a muscle is no longer as active as usual. When muscles are no longer used movement and strength decline causing weakness.

**Neurogenic atrophy:** This most severe type of muscle atrophy occurs when a nerve that connects to the muscle is injured or has a disease. This type of muscle atrophy tends to occur suddenly when compared to disuse atrophy that is more gradual.

### Evidence Review

### Description

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.
Background

Neuromuscular Electrical Stimulation Devices (NMES)

These devices, through multiple channels, attempt to stimulate motor nerves and alternately causes contraction and relaxation of muscles, unlike a TENS device which is intended to alter the perception of pain. NMES are used to prevent or retard disuse atrophy, relax muscle spasm, increase blood circulation, maintain or increase range of motion, and re-educate muscles.

This policy addresses the use of open loop neuromuscular systems which are used for simple tasks such as muscle strengthening alone, and typically in healthy individuals with intact neural control.

Functional neuromuscular stimulators are closed loop systems, which provide feedback information on muscle force and joint position, thus allowing constant modification of stimulation parameters which are required for complex activities such as walking. (These are addressed in a separate policy, see Related Medical Policies.)

The RS 4m and RS 2m muscle stimulator are examples of devices that delivers neuromuscular electric stimulation.

Galvanic Stimulation Devices

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.

H-wave Electrical 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. While physiatrists, chiropractors, or podiatrists may perform H-wave stimulation, 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.

A variety of devices may be used for H-wave stimulation. In general, the FDA has classified them as "powered muscle stimulators." As a class, the FDA describes these devices as "an electronically powered device intended for medical purposes that repeatedly contracts muscles by passing electrical currents through electrodes contacting the affected body area." The H-WAVE® Muscle Stimulator (Electronic Waveform Laboratory, Inc., CA) is FDA 510(k) approved as a class II device.

**Microcurrent Stimulation Devices (MENS)**

MENS is characterized by subsensory current that acts on the body’s naturally occurring electrical impulses in an effort to decrease pain and facilitate the healing process. MENS differs from TENs in that it uses a significantly reduced level of electrical stimulation. TENS blocks pain, while MENS acts on the naturally occurring electrical impulses to decrease pain by stimulating the healing process.

**Pulsed Electrical and Electromagnetic Stimulation Devices**

Pulsed electrical and electromagnetic stimulation are being investigated to improve functional status and to relieve pain related to osteoarthritis (OA) and rheumatoid arthritis (RA) that are unresponsive to other standard therapies. Noninvasive electrical stimulators generate a weak electrical current within the target site using pulsed electromagnetic fields, capacitive coupling, or combined magnetic fields. In capacitive coupling, small skin pads or electrodes are placed on either side of the knee or wrist. Electrical stimulation is provided by an electronic device that noninvasively delivers a subsensory low-voltage, monophasic electrical field to the target site of pain. Pulsed electromagnetic fields are delivered via treatment coils that are placed over the skin. Combined magnetic fields deliver a time-varying magnetic field by superimposing that field onto an additional static magnetic field.

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.

**Sympathetic Stimulation Devices**

Sympathetic therapy describes a type of electrical stimulation of the peripheral nerves that is designed to stimulate the sympathetic nervous system in an effort to “normalize” the autonomic nervous system and alleviate chronic pain. Unlike TENS or interferential electrical stimulation, sympathetic therapy is not designed to treat local pain, but is designed to induce a systemic effect on sympathetically induced pain.

Sympathetic therapy uses four intersecting channels of various frequencies with bilateral electrode placement on the feet, legs, arms, and hands. Based on the location of the patient’s pain and treatment protocols supplied by the manufacturers, electrodes are placed in various locations on the lower legs and feet or the hands and arms. Electrical current is then induced with beat frequencies between 0 and 1000Hz. Treatment may include daily one-hour treatments in the physician’s office, followed by home treatments if the initial treatment is effective.

**Transcutaneous Electrical Modulation Pain Reprocessing (TEMPR) (CPT 0278T)**

Scrambler Therapy/Calmare® device is also known as transcutaneous electrical modulation pain reprocessing (TEMPR). It is an electrocutaneous nerve stimulation device. It uses a biophysical rather than a biochemical approach. It is proposed that a “no-pain” message is transmitted to the nerve via disposable surface electrodes applied to the skin in the region of the patient’s pain. The perception of pain is then cancelled when the no-pain message replaces that of pain, by using the same pathway through the surface electrodes in a non-invasive way. Regardless of pain intensity, a patient’s pain can reportedly be completely removed for immediate relief. Maximum benefit is achieved through follow-up treatments. The patient may be able to go for extended periods of time between subsequent treatments while experiencing significant pain control and relief. The period of time between treatments depends on the underlying cause and severity of the pain in addition to other factors. Treatment utilizing the Calmare® medical device may only be done under the direct supervision of allopathic physicians and other qualified licensed healthcare professionals who are certified in its use and application and are familiar with the principles, clinical applications, side effects and hazards associated with transdermal pain modulation.
Transcutaneous Electrical Nerve Stimulator (Cefaly®)

Cefaly® (STX-Med, Belgium) is a transcutaneous supraorbital nerve stimulator. The device is battery-powered and worn like a headband whereby self-adhesive electrodes are placed on the forehead covering the supratrochlear and supraorbital nerves (branches of the trigeminal nerve). The device is worn for 20 minutes daily. The device reportedly has a neuromodulatory effect on the treated nerves, thereby blocking pain signals. In 2014, the Cefaly® (Cefaly-Technology, Belgium) device received an FDA de novo premarket review pathway with an approved indication for the prophylactic treatment of episodic migraine in individuals 18 years of age or older and then was cleared for marketing in 2016 through the 510(k) process (K122566). In 2017, the Cefaly® Acute and Cefaly® Dual were FDA approved as 510(k) Class II transcutaneous electrical nerve stimulator (TENS) to treat headaches. The Cefaly® Acute is indicated for the acute treatment of migraine in patients with or without aura. The Cefaly® Dual is indicated for the acute treatment of migraine with or without aura as well as the prophylactic treatment of episodic migraine.

Figure 1: Cefaly Acute Device

Summary of Evidence

For individuals who have arthritis who receive pulsed electrical or electromagnetic stimulation, the evidence includes a number of small randomized controlled trials (RCTs). Relevant outcomes are symptoms, functional outcomes, health status measures, and treatment-related morbidity. A review of the literature did not find adequate evidence that use of pulsed electrical or electromagnetic stimulation for the treatment of arthritis improves health outcomes. A 2013 meta-analysis identified 9 randomized sham-controlled trials on treatment of osteoarthritis of the knee. There was some evidence of improved function but no evidence of reduced pain. These conclusions are limited by methodologic shortcomings and inconsistent trial results. More recent randomized controlled trials have also had variable results, which might be related to the different devices and treatment durations used. Additional studies with larger numbers of subjects are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

Treatment of Muscle Atrophy

Coverage of NMES to treat muscle atrophy is limited to the treatment of disuse atrophy where nerve supply to the muscle is intact, including brain, spinal cord and peripheral nerves, and other non-neurological reasons for disuse atrophy. Some examples would be casting or splinting of a limb, contracture due to scarring of soft tissue as in burn lesions, and hip replacement surgery (until orthotic training begins).

Sympathetic Therapy

In 2002 Guido and colleagues studied 20 individuals with chronic pain and peripheral neuropathies treated daily with Dynatron STS for 28 days. Pain was reported as moderate to severe by 11 of 15 individuals prior to treatment, with a decrease in pain reported by six of the individuals at conclusion of the treatment. The author did not report on the reason why five of the 20 individuals did not provide self-reports of pain severity. For the 15 individuals who remained in the study, the authors reported the mean cumulative VAS scores for multiple locations of pain decreased from 107.8 to 45.3. However, drawing conclusions concerning the efficacy of Dynatron STS for the management of chronic, intractable pain is limited due to the small participant population, lack of a randomized control group, placebo effects and lack of data on pain severity in a quarter of the subjects. There is a lack of peer-reviewed literature concerning the efficacy of sympathetic therapy in terms of pain relief or for another indication.
Galvanic Stimulation

A 2009 Cochrane review of electrotherapy concluded that the evidence was of low quality and more studies are needed to reliably establish effectiveness.

H-wave Electrical Stimulation

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.

Microcurrent Stimulation

Bertolucci and Grey (1995) compared the efficacy of MENS therapy to mid-laser and laser placebo treatment of 48 individuals with TMJ pain. There was a difference in pain and functional outcomes between laser and MENS therapy with laser being slightly higher; however, the difference was not statistically significant. There was no data to suggest whether the effect was durable and whether the effects continued with repeated use.

There is a lack of large controlled clinical trials testing the clinical effectiveness of microcurrent electrical nerve stimulation against placebo devices. Therefore, this treatment remains investigational.

Pulsed Electrical Stimulation and Electromagnetic Stimulation

A review of the literature has not found adequate evidence to indicate that the use of pulsed electrical or electromagnetic stimulation for the treatment of arthritis will result in improvements in health outcomes. A well-conducted meta-analysis from 2013 identified 7 randomized sham-
controlled trials on treatment of osteoarthritis of the knee. There was some evidence of an improvement in function but no evidence of an improvement in pain. These conclusions are limited by methodologic limitations and inconsistency of the study results. No published studies for rheumatoid arthritis were identified. This evidence remains insufficient to evaluate the effect of this treatment on health outcomes. Additional study with a larger number of subjects is needed. Therefore, pulsed electrical or electromagnetic stimulation is considered investigational for the treatment of osteoarthritis and rheumatoid arthritis.

Studies in the published medical literature comparing electromagnetic therapy devices with established wound care management are lacking. The studies are limited in sample size with poorly-defined patient selection criteria, and have limited reporting of methodological details. There is little consensus among authors regarding duration of treatment or technique of application. The results of two Cochrane reviews report no evidence of benefit to electromagnetic therapy when used for wound healing. An additional systematic review also found minimal data to support electromagnetic therapy for the treatment of pressure ulcers.

Evidence in the published peer-reviewed scientific literature evaluating pulsed electromagnetic field (PEMF) therapy for conditions other than wound management consists mainly of case series with few randomized controlled trials. PEMF has been used for the treatment of numerous conditions, such as subacromial impingement syndrome, lateral epicondylitis, tinnitus, soft tissue injuries, multiple sclerosis, fibromyalgia, diabetic peripheral neuropathy, plantar fasciitis and for various other conditions related to pain. However, study results are mixed. Some authors report no difference in pain among study groups while others report improvement in various pain parameters after PEMF therapy. In some studies, other treatment modalities were used, making study interpretations and comparisons difficult.

Evidence based guidelines published by the Academy of Neurology (Bril, et al., 2011) do not support electromagnetic field therapy as a treatment for peripheral diabetic neuropathy. The authors noted electromagnetic field treatment is probably not effective for the treatment of peripheral neuropathy.

Transcutaneous Electrical Modulation Pain Reprocessing (TEMPR)

In 2012, Ricci and colleagues reported on a small retrospective study of 73 patients whose pain management had been unsatisfactory with other treatments. The primary objective of the study was to assess efficacy and tolerability of the MC5-A Calmare device. This device is described as “scrambling pain information with ‘no pain’ information in order to reduce the perception of pain intensity.” There was no comparator treatment. The patients were followed for 4 weeks. The
authors reported that the pain score had decreased by 74% after 10 days of treatment. The authors concluded that cutaneous electrostimulation with the MC5-A Calmare device can be proposed as part of a multimodality approach to the treatment of chronic pain. However, they cautioned that further studies on larger numbers of patients are needed to assess its efficacy, to quantify the effects of inter-operator variability, and to compare results obtained from the active device versus those from a sham machine.

In 2015, Moon and colleagues reported on a multicenter analysis which sought to identify which factors are associated with treatment outcomes for Calmare therapy. They gathered data from 3 medical centers on 147 patients with various pain conditions who underwent a minimum of either 3 Calmare therapies on consecutive days or 5 therapies overall. A successful outcome was predefined as ≥50% pain relief on a 0 to 10 numerical rating scale that persisted for longer than 1 month after the last treatment. Overall, the success rate was 38.1%. Variables found to be associated with a positive outcome included the presence of neuropathic or mixed pain, and treatment at either Walter Reed or Seoul National University. Factors that correlated with treatment failure were disease or traumatic/surgical etiologies and antidepressant use. They concluded that a neuropathic or mixed neuropathic-nociceptive pain condition was associated with a positive treatment outcome and suggested that investigators consider these findings when developing selection criteria in clinical trials designed to determine the efficacy of Calmare therapy.

Transcutaneous Electrical Nerve Stimulator (Cefaly)

There is insufficient evidence in the peer-reviewed literature to support TENS for the treatment of migraines, including the use of Cefaly devices. Studies investigating Cefaly are primarily observational in design and include small patient populations with short-term follow-ups. One study, PREMICE, was a double-blind, sham controlled RCT of 67 total patients. The protocol after a one month run in period had the patients use the device daily for three months. There were fewer number of migraine attacks, number of headache days and a decrease in the number of acute antimigraine drugs in the TENS group than in the sham group. However, there was no statistical significance in the reduction of the number of migraine days for the TENS group versus the sham group. Published data from randomized controlled trials with larger patient populations and longer-term outcomes comparing TENS to conventional therapy are needed to establish the effectiveness of TENS/Cefaly for the treatment of migraines.
Ongoing and Unpublished Clinical Trials

Currently ongoing and unpublished trials that may influence this policy are listed in Table 1.

Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tr>
<td><strong>Ongoing</strong></td>
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<tr>
<td>NCT02436590*</td>
<td>A Prospective, Randomized, Double-Blind, Placebo Controlled Study to Evaluate Efficacy and Safety of an Active Pulsed Electromagnetic Field for the Treatment of Osteoarthritis of the Knee</td>
<td>150</td>
<td>Dec 2018</td>
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<tr>
<td>NCT04197284</td>
<td>Determination of the Effectiveness of Certain Physical Methods in the Treatment of Knee Osteoarthritis (BFBOA)</td>
<td>93</td>
<td>Jan 2022</td>
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<tr>
<td><strong>Unpublished</strong></td>
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<tr>
<td>NCT01838954</td>
<td>The Effect of Short-wave Diathermy in Patients with Osteoarthritis of the Hand: A Randomized, Double Blinded, Placebo Controlled Trial</td>
<td>90</td>
<td>Apr 2016 (last updated 04/10/15)</td>
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NCT: national clinical trial.
* Denotes industry-sponsored or cosponsored trial.

Practice Guidelines and Position Statements

Osteoarthritis Research Society International

In 2014, the Osteoarthritis Research Society International published evidence-based consensus guidelines for nonsurgical management of knee osteoarthritis (OA). Twenty-nine treatment modalities were evaluated for four patient groups: knee-only OA, knee-only OA with comorbidities, multijoint OA, and multijoint OA with comorbidities. Neuromuscular electrical stimulation was considered “not appropriate” for all four groups. Evidence consisted of a systematic review and meta-analysis of randomized controlled trials. The quality of the evidence was considered fair.
American Academy of Orthopaedic Surgeons

In 2013, the American Academy of Orthopaedic Surgeons published guidelines on the treatment of OA of the knee. Due to the overall inconsistent finding for electrotherapeutic modalities, the American Academy of Orthopaedic Surgeons did not recommend for or against use in patients with symptomatic knee OA. The strength of the recommendation was inconclusive.

American College of Rheumatology

In 2019, the American College of Rheumatology released guidelines for the management of osteoarthritis of the hand, hip, and knee. The guidelines do not mention pulsed electrical or electromagnetic stimulation, but they recommend against transcutaneous electrical stimulation for patients with knee and/or hip osteoarthritis. In 2015, American College of Rheumatology released recommendations for the treatment of rheumatoid arthritis. All recommended treatments were pharmacologic. Use of electrical stimulation for treating rheumatoid arthritis was not addressed. Updated guidelines are expected in 2020.

National Institute for Health and Care Excellence (NICE)

In 2016, the NICE published guidance on transcutaneous electrical stimulation of the supraorbital nerve for treating and preventing migraine in adults. The recommendation stated, “current evidence on transcutaneous electrical stimulation of the supraorbital nerve for treating and preventing migraine raises no major safety concerns. The evidence on efficacy is limited in quantity and quality.” The guideline also recommended clinicians ensure that patients understand, “the uncertainty about the procedure’s efficacy.”

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

- In 2017, the ActiPatch® (BioElectronics) was cleared for marketing by FDA through the 510(k) process for non-prescription use for adjunctive treatment of plantar fasciitis of the heel and osteoarthritis of the knee. FDA product code: PQY.
• 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 to deliver pulsed electrical stimulation for adjunctive treatment of osteoarthritis of the knee, then later for rheumatoid arthritis of the hand. The FDA originally determined that this device was substantially equivalent to transcutaneous electrical nerve stimulation (TENS) devices. The manufacturer requested reclassification due to the fact that the target tissue is joint tissue, not nerve. In 2006, the FDA reclassified the device as a transcutaneous electrical stimulator for arthritis.\(^1\) The BioniCare system consists of an electronic stimulator device with electrical leads placed over the affected area and held in place with a lightweight, flexible wrap, and self-adhesive fasteners. The battery-powered device delivers small pulsed electrical currents of 0.0- to 12.0-V output. FDA product code: NYN.

• Calmare® Pain Therapy Medical Device was U.S. FDA 510(k)- cleared in 2009 and classified as a multi-channel transcutaneous electrical nerve stimulator (TENS). European CE mark-certified for the treatment of oncologic and neuropathic pain through biophysical stimulation. The Device has five separate channels, convenient dial selectors with five corresponding channel meters, indicator lights and an LCD display to monitor operation. [http://www.calmarett.com/](http://www.calmarett.com/)

• The OrthoCor™ Active Knee System (OrthoCor Medical; acquired by Caerus Corp. in 2016) uses pulsed electromagnetic field energy at a radio frequency 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 shortwave diathermy device for use other than applying therapeutic deep heat (K091996, K092044). 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. The system includes single-use packs (pods) that deliver hot or cold. 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 devices that applies electromagnetic energy at a radio frequency 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. The Palermo device (Ivivi Health Sciences) is a portable battery-operated device. FDA product code: ILX.

• In 2017 The Cefaly® Acute (K171446) and Cefaly® Dual (K173006) were cleared for marketing by the FDA through the 510(K) process as they were determined to be substantially equivalent predicate devices; they are considered Class II Transcutaneous Electrical Nerve Stimulators to treat headaches. Cefafly® was initially cleared for marketing
in 2016 through the 510(k) process (K122566) following a De Novo classification (DEN120019) in 2014. The Cefaly® Acute is indicated for the acute treatment of migraine in patients with or without aura. The Cefaly® Dual is indicated for the acute treatment of migraine with or without aura as well as the prophylactic treatment of episodic migraine; all of the devices are for use in individuals 18 years of age or older. FDA product code: PCC.

References


<table>
<thead>
<tr>
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<th>Comments</th>
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<tr>
<td>09/10/02</td>
<td>Add to Durable Medical Equipment Section - New Policy. Replaces 1.01.13 H-Wave Electrical Stimulation; 1.01.104 (1.01.09) Transcutaneous Electrical Nerve Stimulator (TENS); 1.04.03 Sympathetic Therapy for the Treatment of Pain; 7.01.29 Percutaneous Electrical Nerve Stimulation (PENS)</td>
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<td>Replace Policy - Policy section revised for clarification only.</td>
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<td>10/16/03</td>
<td>Replace Policy - Interferential Stimulation Devices description updated; references added. No change to policy statement.</td>
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<td>Replace Policy - TMJ as investigational for TENS was added. This is consistent with TMJ policy.</td>
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<td>06/08/04</td>
<td>Replace Policy - Policy reviewed; No change to policy statement.</td>
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<tr>
<td>07/13/04</td>
<td>Replace Policy - Description of PENS revised; information on percutaneous neuromodulation included; policy statement revised to indicate that percutaneous</td>
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<td>Date</td>
<td>Comments</td>
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<td>Replace Policy - Policy renumbered from PR.1.01.107. No date changes.</td>
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<td>09/14/04</td>
<td>Replace Policy - Policy statement revised by adding pulsed electrical stimulation with the BioniCare® to be considered investigational as a treatment for osteoarthritis. Rationale Section updated.</td>
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<td>12/14/04</td>
<td>Replace Policy - Description of TENS revised; information on dementia added; reference added; Medicare policy language on TENS added. No change to policy statement.</td>
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<td>02/08/05</td>
<td>Replace Policy - RS-4i Sequential Stimulator information added. No change to policy statement.</td>
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<td>05/31/05</td>
<td>Update only to web - HCPCS codes added only—no other changes and not presented to MPC.</td>
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<tr>
<td>09/13/05</td>
<td>Replace Policy - Interferential Stimulation and PENS/ PNT added to Rationale section. References updated; no change to policy statement.</td>
</tr>
<tr>
<td>02/06/06</td>
<td>Codes updated - No other changes.</td>
</tr>
<tr>
<td>05/26/06</td>
<td>Update Scope and Disclaimer - No other changes.</td>
</tr>
<tr>
<td>07/11/06</td>
<td>Replace Policy - Update description to include detail of RS 4M and RS 2M muscle stimulators; no change to policy statement.</td>
</tr>
<tr>
<td>04/10/07</td>
<td>Cross Reference Update - No other changes.</td>
</tr>
<tr>
<td>06/12/07</td>
<td>Replace Policy - Policy updated with literature review; references added. No changes in policy statement. Reviewed by practicing orthopedic surgeon in May 2007.</td>
</tr>
<tr>
<td>05/13/08</td>
<td>Replace Policy - Policy updated with literature search. Policy statement was updated to include cranial electrostimulation therapy is considered investigational for all indications listed. The manufacturer provided many articles to be reviewed. Many of them were from the 1990s and earlier. Most of the later studies were not regarding the FDA approved labeled indications. Additional and much larger double-blinded, sham controlled studies are needed to document long-term effects of CES. References and code added to support the update.</td>
</tr>
<tr>
<td>01/13/09</td>
<td>Code Update - Code E0770 added, effective 1/1/09.</td>
</tr>
<tr>
<td>08/11/09</td>
<td>Replace Policy - Policy updated with literature search; references added. No change to policy statement.</td>
</tr>
<tr>
<td>04/13/10</td>
<td>Cross Reference Update - No other changes.</td>
</tr>
<tr>
<td>06/08/10</td>
<td>Replace Policy - Policy updated with literature search, reference added. Added medically necessary statement re: conductive garment and TENS/IF. Also included Flex IT to investigational statement.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>06/13/11</td>
<td>Replace Policy - Policy updated with literature search, reference added. No change to policy statement.</td>
</tr>
<tr>
<td>01/25/12</td>
<td>HCPCS codes S8130 and S8131 added to policy.</td>
</tr>
<tr>
<td>01/26/12</td>
<td>CPT code 0278T added.</td>
</tr>
<tr>
<td>03/13/12</td>
<td>Replace policy. Policy revised by removing indications, descriptions, and rationale addressed in separate policies: 1.01.13, 1.01.24, 1.01.27, 7.01.29, and 8.01.58. Policy now addresses TENS, open loop neuromuscular electrical stimulation, galvanic, microcurrent, cranial electrostimulation and sympathetic electrical stimulation devices.</td>
</tr>
<tr>
<td>04/17/12</td>
<td>Related Policies updated; 7.01.546 added to replace 7.01.25 which has been deleted.</td>
</tr>
<tr>
<td>08/24/12</td>
<td>Update Related Policies. Change title for 7.01.106</td>
</tr>
<tr>
<td>11/20/12</td>
<td>Update Related Policies. Add 8.01.58.</td>
</tr>
<tr>
<td>02/11/13</td>
<td>Replace policy. Removed information on cranial electrostimulation which is addressed in Medical Policy 8.01.58. Added policy statement on scrambler therapy.</td>
</tr>
<tr>
<td>12/30/13</td>
<td>Coding update. HCPCS code E0762 removed; this is addressed in policy No. 1.01.27, Electrical Stimulation for the Treatment of Arthritis. Remove Related Policy 1.01.19; it was archived effective 12/9/13.</td>
</tr>
<tr>
<td>03/21/14</td>
<td>Update Related Policies. Delete 7.01.106 and replace with 7.01.553.</td>
</tr>
<tr>
<td>05/12/14</td>
<td>Annual Review. TENS policy statements and information removed. Added references 3 and 4.</td>
</tr>
<tr>
<td>06/09/14</td>
<td>Interim update. HCPCS codes E0720, E0730 and E0731 are no longer reviewed and from the policy. The Policy section has been updated with removal of the policy statement related to code E0730 and the TENS unit.</td>
</tr>
<tr>
<td>03/10/15</td>
<td>Annual Review. Policy updated with literature search through November 2014. Added statement from medical policy 1.01.27 (that is now archived) “Electrical stimulation is considered investigational for the treatment of osteoarthritis or rheumatoid arthritis” along with the HCPCS code. Added policy 7.01.529, removed policy 1.01.27 from Related Policies section. Added information about conductive garment to the Policy Guidelines. Added Definition of Terms to Policy Guidelines. Regulatory Status section updated with additional device names. Reference 6-12, 14 added; others renumbered. Added code E0762. Policy statement added as noted. Coding update: CPT codes 64553-64590 removed as there are more specific codes listed; HCPCS codes S8130, S8131 removed as these are not being utilized; HCPCS codes E0770 and L8680 removed as these are listed on other policies to which they apply.</td>
</tr>
<tr>
<td>04/17/15</td>
<td>Update Related Policies. Remove 7.01.553 and 7.01.529 as they were archived, and add 7.01.07.</td>
</tr>
<tr>
<td>01/12/16</td>
<td>Annual Review. Policy updated with literature search through November 2015. No studies were found which would prompt a change in the policy statement. References added.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>------------</td>
<td>---------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>01/29/16</td>
<td>Minor update. Add code L8679 to coding table.</td>
</tr>
<tr>
<td>06/01/17</td>
<td>Annual Review, approved May 23, 2017. Put into new format. No changes to policy statement.</td>
</tr>
<tr>
<td>08/01/18</td>
<td>Interim Review, approved July 10, 2018. Policy updated with literature review through June 2018. References 24-32 added. Policy statement modified to “Pulsed electrical stimulation and pulsed electromagnetic therapy are considered investigational for any indication including, but not limited to the treatment of osteoarthritis, rheumatoid arthritis, neuropathic pain (diabetic peripheral neuropathy), post-operative or non-post-operative pain, or to treat wounds.”</td>
</tr>
<tr>
<td>06/01/20</td>
<td>Annual Review, approved May 12, 2020. Policy updated with literature review through January 2020; references added. Added H-wave electrical stimulation and transcutaneous supraorbital electrical nerve stimulator are considered investigational. Otherwise, policy statements unchanged. HCPCS code E0761 was added.</td>
</tr>
<tr>
<td>08/01/20</td>
<td>Update Related Policies. Add 1.01.24 Interferential Current Stimulation.</td>
</tr>
</tbody>
</table>

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2020 Premera All Rights Reserved.

**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.
Discrimination is Against the Law

LifeWise Health Plan of Washington complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. LifeWise does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

LifeWise:
• Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  • Qualified sign language interpreters
  • Written information in other formats (large print, audio, accessible electronic formats, other formats)
• Provides free language services to people whose primary language is not English, such as:
  • Qualified interpreters
  • Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that LifeWise has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:
Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-6396, Fax 425-918-5592. TTY 800-842-5357
Email AppealsDepartmentInquiries@LifeWiseHealth.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the http://www.hhs.gov/ocr/office/index.html, or by mail or phone at:
U.S. Department of Health and Human Services, Office for Civil Rights, 200 Independence Avenue SW, Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)


Getting Help in Other Languages

This Notice has Important Information

This Notice has Important Information. This notice may have important information about your application or coverage through LifeWise Health Plan of Washington. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-592-6804 (TTY: 800-842-5357).

Oromo (Cushite):

Français (French):

Deutsche (German):

Italiano (Italian):

中文 (Chinese):
本通知有重要的訊息。本通知可能有關於您透過LifeWise Health Plan of Washington提交的申請或保險的重要訊息。本通知內在重要日期，您可能會需要在截止日期之前採取行動，以保留您的健康保險或費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話 800-592-6804 (TTY: 800-842-5357).
Japanese (Japanese):

この通知には重要な情報が含まれています。この通知には、LifeWise Health Plan of Washingtonの申請または補償範囲に関する重要な情報が含まれています。この通知に記載されている可能性がある重要な内容をご確認ください。健康保険や保険料を維持するには、特定の日限までに行動を取りなければならない場合があります。ご希望の言語による情報とサポートが無料で提供されます。800-592-6804 (TTY: 800-842-5357) までお電話ください。

Korean (Korean):

본 통지서에 중요한 정보가 들어 있습니다. 즉 이 통지서는 귀하의 신청에 관하여 그리 LifeWise Health Plan of Washington을 통한 커버지를 지원하는 정보를 포함하고 있을 수 있습니다. 본 통지서에는 핵심이 되는 날짜들이 있을 수 있습니다. 귀하의 모든 커버지를 계속 유지하고자 비용을 절약하기 위해서 일정한 마감일까지 조치를 취해야 할 필요가 있을 수 있습니다. 귀하의 이러한 정보와 커버지를 얻는 데 필요한 비용 부담없이 알 수 있는 권리가 있습니다。800-592-6804 (TTY: 800-842-5357) 로 전화하십시오。

Vietnamese (Vietnamese):

e thông báo này. Quý vui lòng gọi 800-592-6804 (TTY: 800-842-5357) để được hỗ trợ.

Spanish (Spanish):

Este aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de LifeWise Health Plan of Washington. Es posible que haya fechas clave en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-592-6804 (TTY: 800-842-5357).

Tagalog (Tagalog):


Thai (Thai):

ประกาศนี้มีข้อมูลสําคัญเพื่อประหยัดและซื้อสิทธิ์ โดยใช้ภาษาไทยที่หากต้องการข้อมูลเพิ่มเติมในการติดต่อเราที่ numbers listed on the back page.

Ukrainian (Ukrainian):

Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо страхувального покриття через LifeWise Health Plan of Washington. Звернеться у вашу клієнтську дівізію із атомото, які можуть бути вказані у цьому повідомленні. Існує імовірність того, що Вам треба буде здійснити певні кроки у конкретні нічні строки для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дозвоніться за номером телефону 800-592-6804 (TTY: 800-842-5357).

Vietnamese (Vietnamese):


Română (Romanian):


Русский (Russian):

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