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Medicare Advantage Policy Manual

Policy ID: M-DME83

## **Electrical Stimulation and Electromagnetic Therapy Devices**

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### **IMPORTANT REMINDER**

*The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member, including care that may be both medically reasonable and necessary.*

*The Medicare Advantage medical policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and Centers of Medicare and Medicaid Services (CMS) policies and manuals, along with general CMS rules and regulations. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of a specific CMS coverage determination for a requested service, item or procedure, the health plan may apply CMS regulations, as well as their Medical Policy Manual or other applicable utilization management vendor criteria developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.*

*Some services or items may appear to be medically indicated for an individual, but may be a direct exclusion of Medicare or the member's benefit plan. Medicare and member EOCs exclude from coverage, among other things, services or procedures considered to be investigational (experimental) or cosmetic, as well as services or items considered not medically reasonable and necessary under Title XVIII of the Social Security Act, §1862(a)(1)(A). In some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services. Members, their appointed representative, or a treating provider can request coverage of a service or item by submitting a pre-service organization determination prior to services being rendered.*

### **DESCRIPTION**

A variety of electrical stimulation (electrostimulation) and electromagnetic therapy devices and treatments are available. They are used to relieve acute and chronic pain, alleviate symptoms caused by other medical conditions, treat muscle atrophy, provide ambulation in patients with a spinal cord injury, or in the treatment of wounds.

## MEDICARE ADVANTAGE POLICY CRITERIA

**NOTES:**

- Electrical stimulation or electromagnetic devices and procedures which require prior authorization are found on our “*Medicare Pre-authorization List*” web page. Note that some electrical stimulation services may be reviewed externally by a vendor.
- Specific electrostimulation and/or electromagnetic codes **not** listed on the prior authorization website do not require prior approval and may be considered medically necessary for Medicare Advantage.
- Some forms of electrical stimulation may be addressed in other Medicare Advantage medical policies (see Cross References).
- Providers remain responsible for correct coding, billing practices, and medical necessity whether or not there is a policy in place.

Type of Stimulation:	HCPCS Code(s)	CMS Coverage Manuals, National Coverage Determinations (NCD), and Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCD) and Articles*	Medical Policy Manual
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**ELECTRICAL STIMULATION DEVICES ADDRESSED BY THIS MEDICARE ADVANTAGE MEDICAL POLICY:**

<b>Galvanic Stimulation</b>	E1399	<b><i>Electrotherapy for Treatment of Facial Nerve Paralysis (Bell’s Palsy)</i></b>	<a href="#">NCD 160.15</a>	<p><i>Other than what is cited, Medicare coverage guidance is not available for galvanic electrical stimulation. Therefore, the health plan’s medical policy is applicable for some indications.</i></p> <p><b>For <i>all other indications not previously addressed</i>:</b></p> <p>Galvanic Stimulation, Durable Medical Equipment, <a href="#">Policy No. 83.01</a></p>
		<b><i>Electrical Stimulation (ES) and Electromagnetic Therapy for the Treatment of Wounds</i></b>	<a href="#">NCD 270.1</a>	
		<b><i>Nerve Blockade for Treatment of Chronic Pain and Neuropathy- For treatment of peripheral neuropathy</i></b>	<a href="#">LCD L35457</a>	
<b>H-wave Stimulation</b>	E1399	<b><i>Electrical Stimulation (ES) and Electromagnetic Therapy for the Treatment of</i></b>	<a href="#">NCD 270.1</a>	

Type of Stimulation:	HCPCS Code(s)	CMS Coverage Manuals, National Coverage Determinations (NCD), and Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCD) and Articles*	Medical Policy Manual						
		<table border="1"> <tr> <td data-bbox="863 331 1335 370"><b>Wounds</b></td> <td data-bbox="1335 331 1543 370"></td> </tr> <tr> <td data-bbox="863 370 1335 581"><b>Nerve Blockade for Treatment of Chronic Pain and Neuropathy-</b> For treatment of peripheral neuropathy</td> <td data-bbox="1335 370 1543 581"><a href="#">LCD L35457</a></td> </tr> </table> <p data-bbox="856 597 1549 678">For the <b>treatment of all other indications not otherwise addressed by NCD or LCD:</b></p> <table border="1"> <tr> <td data-bbox="863 686 1335 776"><b>Neuromuscular Electrical Stimulation (NMES)</b></td> <td data-bbox="1335 686 1543 776"><a href="#">NCD 160.12</a></td> </tr> </table>	<b>Wounds</b>		<b>Nerve Blockade for Treatment of Chronic Pain and Neuropathy-</b> For treatment of peripheral neuropathy	<a href="#">LCD L35457</a>	<b>Neuromuscular Electrical Stimulation (NMES)</b>	<a href="#">NCD 160.12</a>	
<b>Wounds</b>									
<b>Nerve Blockade for Treatment of Chronic Pain and Neuropathy-</b> For treatment of peripheral neuropathy	<a href="#">LCD L35457</a>								
<b>Neuromuscular Electrical Stimulation (NMES)</b>	<a href="#">NCD 160.12</a>								
<b>Microcurrent Stimulation (MENS)</b>	E1399	<table border="1"> <tr> <td data-bbox="863 792 1335 963"><b>Electrical Stimulation (ES) and Electromagnetic Therapy for the Treatment of Wounds</b></td> <td data-bbox="1335 792 1543 963"><a href="#">NCD 270.1</a></td> </tr> <tr> <td data-bbox="863 963 1335 1133"><b>Nerve Blockade for Treatment of Chronic Pain and Neuropathy-</b>For treatment of peripheral neuropathy</td> <td data-bbox="1335 963 1543 1133"><a href="#">LCD L35457</a></td> </tr> </table>	<b>Electrical Stimulation (ES) and Electromagnetic Therapy for the Treatment of Wounds</b>	<a href="#">NCD 270.1</a>	<b>Nerve Blockade for Treatment of Chronic Pain and Neuropathy-</b> For treatment of peripheral neuropathy	<a href="#">LCD L35457</a>	<p data-bbox="1570 800 1934 1076">Other than what is cited, Medicare coverage guidance is not available for microcurrent electrical stimulation. Therefore, the health plan's medical policy is applicable for some indications.</p> <p data-bbox="1570 1101 1934 1430">For the <b>treatment of all other indications:</b> Microcurrent Stimulation (MENS), Durable Medical Equipment, <a href="#">Policy No. 83.03</a> (see "NOTE" below)</p>		
<b>Electrical Stimulation (ES) and Electromagnetic Therapy for the Treatment of Wounds</b>	<a href="#">NCD 270.1</a>								
<b>Nerve Blockade for Treatment of Chronic Pain and Neuropathy-</b> For treatment of peripheral neuropathy	<a href="#">LCD L35457</a>								

Type of Stimulation:	HCPCS Code(s)	CMS Coverage Manuals, National Coverage Determinations (NCD), and Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCD) and Articles*	Medical Policy Manual
<b>Functional Neuromuscular Electrical Stimulation</b>	A4544, A4560, E0731, E0743, E0744, E0745, E0764, E0770	<b>Neuromuscular Electrical Stimulation (NMES)</b>	<a href="#">NCD 160.12</a>
		<b>Clarification regarding coverage for FES</b>	<a href="#">Functional Electrical Stimulation - Coverage and HCPCS Coding – Revised</a>
		<b>Supplies Used in the Delivery of TENS and NMES</b>	<a href="#">NCD 160.13</a>
		<b>Nerve Blockade for Treatment of Chronic Pain and Neuropathy</b> -For treatment of peripheral neuropathy	<a href="#">LCD L35457</a>
<b>Threshold Electrical Stimulation</b>	E1399, K1018, K1019	<b>Neuromuscular Electrical Stimulation (NMES)</b>	<a href="#">NCD 160.12</a>
		<b>Treatment of Motor Function Disorders with Electric Nerve Stimulation-</b> For all other motor function disorders and	<a href="#">NCD 160.2</a>

Type of Stimulation:	HCPCS Code(s)	CMS Coverage Manuals, National Coverage Determinations (NCD), and Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCD) and Articles*	Medical Policy Manual
		for wrist-worn devices (e.g., Cala Trio™; HCPCS K1018, K1019)	
<b><i>Cranial Electrostimulation Therapy (CES)</i></b>	A4596, E1399, K1002		<p><i>Medicare coverage guidance is not available for Cranial Electrostimulation Therapy (CES). Therefore, the health plan's medical policy is applicable for some indications.</i></p> <p><b>For <i>all other indications not previously addressed</i>:</b></p> <p>Cranial Electrostimulation Therapy (CES), Durable Medical Equipment, <a href="#">Policy No. 83.06</a></p>
<b><i>Electrostimulation and Electromagnetic Therapy for Wounds</i></b>	E0761, E0769, G0281, G0282, G0295, G0329	<p><b><i>Electrical Stimulation and Electromagnetic Therapy for the Treatment of Wounds</i></b></p> <p><a href="#">NCD 270.1</a></p>	
<p>“Medicare will not cover the device used for the electrical stimulation for the treatment of wounds. However, Medicare will cover the service. Unsupervised home use of electrical stimulation will not be covered.”<sup>[1]</sup></p>			

Type of Stimulation:	HCPCS Code(s)	CMS Coverage Manuals, National Coverage Determinations (NCD), and Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCD) and Articles*	Medical Policy Manual		
		<p>“Medicare will not cover the device used for the electromagnetic therapy for the treatment of wounds. However, Medicare will cover the service. Unsupervised home use of electromagnetic therapy will not be covered.” [8]</p>			
<p><b><i>Intraoperative Electrical Stimulation for Peripheral Nerve Regeneration</i></b></p>	<p>0882T 0883T</p>		<p><u>Medicare coverage guidance is not available for electrical stimulation for intraoperative peripheral nerve regeneration</u></p> <p><b>For treatment of all indications:</b></p> <p>Electrical Stimulation for the Treatment of Wounds, <a href="#">Policy No. 83.09</a></p>		
<p><b><i>Electrical Stimulation and Electromagnetic Therapy for Arthritis</i></b></p>	<p>E0762</p>	<table border="1"> <tr> <td data-bbox="865 945 1335 1032"><b><i>Transcutaneous Electrical Joint Stimulation Devices</i></b></td> <td data-bbox="1335 945 1541 1032"><a href="#">LCD L34821</a></td> </tr> </table>	<b><i>Transcutaneous Electrical Joint Stimulation Devices</i></b>	<a href="#">LCD L34821</a>	
<b><i>Transcutaneous Electrical Joint Stimulation Devices</i></b>	<a href="#">LCD L34821</a>				
<p><b><i>Transcutaneous Electrical Modulation Pain Reprocessing (TEMPR)</i></b></p>	<p>0278T K1023</p>		<p><i>Medicare coverage guidance is not available for TEMPR. Therefore, the health plan’s medical policy is applicable for some indications.</i></p> <p>Transcutaneous Electrical Modulation Pain Reprocessing,</p>		

<b>Type of Stimulation:</b>	<b>HCPCS Code(s)</b>	<b>CMS Coverage Manuals, National Coverage Determinations (NCD), and Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCD) and Articles*</b>	<b>Medical Policy Manual</b>
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Medicine, [Policy No. 143](#)

**Non-Implantable (External) Trigeminal Nerve Stimulation (eTNS)**    K1016, K1017    Medicare coverage for TENS devices is limited to pain-related indications. See rows below for the health plan’s policy position for TENS units used for the treatment of pain. TENS devices used for indications **other than** pain, including attention deficit hyperactivity disorder (ADHD), do not meet Medicare’s medically reasonable and necessary criteria and are non-covered. Medicare references for TENS include:

<b>TENS for Acute Post-Operative Pain</b>	<a href="#">NCD 10.2</a>
<b>TENS for Chronic Low Back Pain</b>	<a href="#">NCD 160.27</a>
<b>TENS</b>	<a href="#">LCD L33802</a>

**Electrical Stimulation for Essential Tremor**    E0734, A4542    **External Upper Limb Tremor Stimulator Therapy**    [LCD L39591](#)

**ELECTRICAL STIMULATION DEVICES NOT INCLUDED WITHIN THE SCOPE OF THIS POLICY:**

**Sympathetic Electrical Stimulation Therapy** – E1399

**Transcutaneous Electrical Nerve Stimulation (TENS) for Pain** – E0720, E0730, E0731

**Interferential Current Stimulation (IFC or IFS)** – E0730, E0745,<sup>[6, 7]</sup> E1399, S8130, S8131

(Note: If the device is provided as an NMES/FES device, it should be reported as E0745 and the FES/NMES criteria above will be applied.)

*Electrical stimulation devices not otherwise addressed in this or another Medicare Advantage policy, when not included on the our “Medicare Pre-authorization List” web page, including those listed to the left, may be considered medically necessary for Medicare Advantage if the HCPCS code(s) used is/are otherwise eligible for Medicare coverage (e.g., S-codes are not payable by Medicare and therefore, would not be eligible for coverage) and when Medicare coverage criteria for the device in question are met. While these devices may not be routinely reviewed for medical necessity, they may be subject to utilization audit.*

Type of Stimulation:	HCPCS Code(s)	CMS Coverage Manuals, National Coverage Determinations (NCD), and Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCD) and Articles*	Medical Policy Manual
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**NOTE:** According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an **objective, evidence-based process, based on authoritative evidence**. ([Medicare IOM Pub. No. 100-16, Ch. 4, §90.5](#)). The Medicare Advantage Medical Policy – Medicine Policy No. M-149 – provides further details regarding the plan’s evidence-assessment process (see Cross References).

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\*\*Scroll to the “Public Version(s)” section at the bottom of the Article or LCD for links to prior versions if necessary.

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## POLICY GUIDELINES

### REQUIRED DOCUMENTATION

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome:

- All chart notes and medical records pertinent to the request, including history and physical documenting the condition being treated and symptoms experienced.
- Type of planned electrical stimulation and device name.
- If the electrical stimulation is being used to treat wounds, the clinical documentation must include the *type* and *stage* of wound, attempted standard wound therapy, and whether or not measurable signs of improved healing exist (see Medicare NCD 270.1).

### BACKGROUND

#### Galvanic Stimulation

Galvanic stimulation describes unidirectional electrical current between two electrodes placed on the skin. It has been proposed as a treatment for various conditions, including inflammation, pain, and nausea. It is proposed to work by facilitating ion movement under the skin, promoting circulation near the negative electrode, while reducing circulation near the positive electrode. It is theorized that these changes in circulation promote wound healing, reduce edema and inflammation, and decrease pain. Finally, galvanic stimulation is also proposed to work on the vestibular nerve to help with balance and nausea.

#### H-wave Stimulation

H-wave stimulation is a distinct form of electrical stimulation that creates muscle contractions, and differs from other forms of electrical stimulation (i.e., transcutaneous electrical nerve stimulation, or TENS) due to the difference in waveform. The proposed mechanism of H-wave stimulation is a bipolar, exponential decaying waveform that combines low and high frequency wave lengths, which are projected to provide muscle stimulation and analgesic pain control.

#### Microcurrent Stimulation (MENS)

A microcurrent electrical neuromuscular or nerve stimulation (MENS) device is characterized by tiny, sub-sensory currents, which are described as being similar to the body's naturally occurring electrical impulses. MENS devices are proposed to decrease pain and facilitate the healing process.

#### Functional Neuromuscular Electrical Stimulation

“The type of NMES that is use[d] to enhance the ability to walk of SCI patients is commonly referred to as functional electrical stimulation (FES). These devices are surface units that use electrical impulses to activate paralyzed or weak muscles in precise sequence...” (*Medicare NCD 160.12*) Functional neuromuscular electrical stimulation may also be referred to as Neuromuscular Electrical Stimulation (NMES), Functional Neuromuscular Stimulation (FNS), Functional Electrical Stimulation (FES), Electrical Neuromuscular Stimulation (ENS), or electromyography (EMG)-triggered neuromuscular stimulation.

### **Threshold Electrical Stimulation**

Threshold electrical stimulation is the delivery of low intensity electrical stimulation to target spastic muscles during sleep at home. The stimulation is not intended to cause muscle contraction, and has been proposed as a treatment for motor disorders. 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.

### **Cranial Electrostimulation Therapy (CES)**

Cranial electrostimulation therapy (CES), also called cranial electrotherapy stimulation, involves passing small electrical impulses across the head, usually from electrodes placed on or near both ears. CES is proposed for use in treating a variety of chronic conditions including, but not limited to stress, alcoholism and drug addiction, headache, cognitive dysfunction in head injured patients, psychiatric conditions, reflex sympathetic dystrophy and multiple sclerosis.

### **Electrostimulation and Electromagnetic Therapy for Wounds**

Electrical stimulation, or ES, as well as electromagnetic therapy have been proposed for many different applications, one of which is accelerating wound healing. “ES for the treatment of wounds is the application of electrical current through electrodes placed directly on the skin in close proximity to the wound. Electromagnetic therapy uses a pulsed magnetic field to induce current.” (*National Coverage Determination 270.1*)

### **Electrical Stimulation and Electromagnetic Therapy for Arthritis**

“Transcutaneous electrical joint stimulation is administered by a noninvasive device that delivers electrical stimulation intended to reduce the level of pain and symptoms associated with arthritis in a joint.” (*Noridian LCD L34821*)

### **Sympathetic Electrical Stimulation Therapy**

Sympathetic electrical stimulation therapy (aka, sympathetic therapy) is a type of electrical stimulation of the peripheral nerves designed to stimulate the sympathetic nervous system in

an effort to “normalize” the autonomic nervous system and alleviate chronic pain. Unlike TENS (transcutaneous electrical nerve stimulation) 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.

### **Interferential Current Stimulation (IFC or IFS)**

Interferential current stimulation (IFC or IFS) is a type of transcutaneous electrical stimulation (TENS) believed to permeate the tissues more effectively and with less unwanted stimulation of cutaneous nerves, making it more comfortable than TENS. IFC has been investigated primarily as a technique to reduce pain but has also been proposed to increase function of patients with osteoarthritis and to treat other conditions such as dyspepsia, irritable bowel syndrome, and constipation.

### **Transcutaneous Electrical Modulation Pain Reprocessing (TEMPR)**

Transcutaneous electrical modulation pain reprocessing (TEMPR) (aka “scrambler Therapy”) is a pain treatment involving a sequence of treatments with electrical stimulation in the office setting. While it uses a type of transcutaneous electrical stimulation (TENS) device specifically designed for this therapy, unlike conventional TENS, TEMPR is administered in the office setting under physician supervision.

### **Non-Implantable Trigeminal Nerve Stimulation**

Examples of such devices include the Monarch external Trigeminal Nerve Stimulation (eTNS) System (NeuroSigma), a non-implantable Trigeminal Nerve Stimulation device indicated for the treatment of pediatric ADHD as a standalone therapy (monotherapy) in patients ages 7 through 12 years old who are not currently taking prescription ADHD medications. This device requires periodic replacement of components, such as the Monarch NS-2 Electric Patch Pouch. The Monarch eTNS System sends a low-level electrical pulse through a wire to a small patch adhered to the patient’s forehead during periods of sleep. The therapeutic pulses stimulate the branches of the trigeminal nerve, which activates the neural pathway to other parts of the brain thought to be involved in ADHD. Neuroimaging studies have shown that eTNS increases activity in brain regions that are known to be important in regulating attention, emotion, and behavior. This device was approved through the FDA’s 510(k) premarket process, which allows devices to obtain marketing authorization by demonstrating substantial equivalence to a predicate device.

### **Electrical Stimulation for Essential Tremor**

External upper limb tremor stimulator therapy, also known as transcutaneous afferent patterned stimulation (TAPS) therapy, is indicated to reduce essential tremor symptoms using

60-minute therapy sessions. An external upper limb tremor stimulator is a prescription device which is placed externally on the upper limb and designed to aid in tremor symptom relief of the upper limb. Examples of these devices include Cala ONE and Cala Trio. Cala ONE received de novo classification as a Class II device from the US FDA in 2018. Cala ONE is a wrist-worn stimulator which applies transcutaneous electrical stimulation non-invasively to the median and radial nerves through disposable hydrogel electrodes. Cala Trio was approved as substantially equivalent to Cala ONE through the FDA 510(k) premarket approval process and is indicated to aid in the temporary relief of hand tremors in the treated hand following stimulation in adults with essential tremor.

## REGULATORY STATUS

While not an all-inclusive list, the following are examples of electrical stimulation or electromagnetic therapy devices that have been cleared for marketing by the U.S. Food and Drug Administration (FDA).

Of note, the fact a service or procedure has been FDA approved for a specific indication does not, in itself, make the procedure medically reasonable and necessary. Medicare contractors evaluate services, procedures, drugs or technology to determine if they may be considered Medicare covered services. The FDA determines safety and effectiveness of a device or drug, but does not establish medical necessity. While Medicare may adopt FDA determinations regarding safety and effectiveness, CMS or Medicare contractors evaluate whether or not the drug or device is reasonable and necessary for the Medicare population under §1862(a)(1)(A).

Device	Type of ES	Manufacturer
H-Wave <sup>®</sup> [1,2]	H-Wave	
Alpha-Stim PPM <sup>®</sup> (personal pain manager)	MENS	
Parastep <sup>®</sup> Ambulation System	FES/NMES	Sigmedics
ReWalk <sup>™</sup>	FES/NMES	ReWalk <sup>™</sup> Bionics Research Inc.
Neurocontrol Freehand <sup>®</sup> system ( <i>no longer available</i> )	FES/NMES	
NESS H200 <sup>®</sup> ( <i>previously the Handmaster NMS I system</i> )	FES/NMES	
WalkAide <sup>®</sup>	FES/NMES	Innovative Neurotronics (formerly NeuroMotion, Inc.)
Radio-frequency controlled NESS L300 <sup>™</sup>	FES/NMES	Bioness
MyGait	FES/NMES	Otto Bock HealthCare
Foot Drop Stimulator	FES/NMES	Odstock Medical Limited
RT300	FES/NMES	Restorative Therapies, Inc.
Alpha-Stim <sup>®</sup> Cs	CES	Electromedical Products, Inc.
BR-2 Biorest	CES	Biorest, Inc.

Biotron18	CES	Biotronics Corp.
CES Ultra™	CES	Neuro-Fitness, LLC
Elexoma Medic	CES	Redplane AG
FM 10/C	CES	Johari Digital Healthcare, Ltd
HP-1 Healthpax or Nurtipax	CES	Health Directions, Inc.
LB-2000	CES	Life Balance Intl., Inc
LISS SBI202-B and SBI201-M	CES	Medical Consultants Intl., Ltd
NET-2000 Microcurrent Stimulator	CES	Auri-Stim Medical, Inc.
NF-1 Mindpeace	CES	NeuroFitness
NH 2002	CES	Life Balance Intl., Inc.
NTI-1000	CES	Neurotek, Inc.
TESA-1	CES	Kalaco Scientific, Inc.
Dynatron STS device and Dynatron STS RX (the latter is the companion home device)	Sympathetic ES	Dynatronics Corp.
Medstar™ 100	IFC/IFS	MedNet Services
RS-4i®	IFC/IFS	RS Medical
IF-4000	IFC/IFS	Apex Medical Corporation
Calmare® Pain Therapy device	TEMPR	Competitive Technologies, Inc.
Monarch external Trigeminal Nerve Stimulation (eTNS) System	Trigeminal nerve stimulator	NeuroSigma
Cala ONE and Cala Trio	TAPS	Cala Health, Inc.

## Threshold Electrical Stimulation

Devices used for threshold electrical stimulation are classified as “powered muscle stimulators.” As a class, the U.S. Food and Drug Administration (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.” There are currently more than 30 devices with 510(k) approval from the FDA, including the Cala Trio™ (Cala Health) neuromodulation device, which is a wrist-worn peripheral nerve stimulation device, indicated to aid in the transient relief of hand tremors in the treated hand following stimulation in adults with essential tremor.

## Electrostimulation and Electromagnetic Therapy for Wounds

At the present time there are no electrical stimulation devices that have received U.S. Food and Drug Administration (FDA) approval specifically for the treatment of wound healing. A number of devices have been cleared for marketing for other indications. Use of these devices for wound healing is an off-label indication.

## Electrical Stimulation and Electromagnetic Therapy for Arthritis

Devices with U.S. Food and Drug Administration (FDA) 510(k) clearance for adjunctive treatment of knee pain in osteoarthritis, include:

- RS-4i® Sequential Stimulator (RS Medical)
- OrthoCor™ Active Knee System (OrthoCor Medical)

Devices which have received 510(k) clearance for the treatment of rheumatoid arthritis of the hand, in addition to osteoarthritis of the knee, include:

- MedRelief® ST Series™: ST-150, ST-200 and ST-300 (Healthonics, Inc.).
- BioniCare BIO-1000™ (BioniCare Medical Technologies, Inc.).

Devices which have received 510(k) clearance for adjunctive use in the palliative treatment of postoperative pain and edema in superficial soft tissue include:

- The SofPulse™ (also Torino II, 912-M10, and Roma3™, Ivivi Health Sciences).

“HCPCS code E0762 is used to bill Medicare for a transcutaneous electrical joint stimulation device system. The only products that may be billed using this code are those that have undergone Coding Verification Review by the SADMERC and that are listed in the DMECS Product Classification List on the SADMERC web site.”

## CROSS REFERENCES

[Bone Growth Stimulators \(Osteogenic Stimulation\)](#), Durable Medical Equipment, Policy No. M-83.12

[Auricular Electrostimulation](#), Medicine, Policy No. M-146

[Transcranial Magnetic Stimulation as a Treatment of Depression and Other Disorders](#), Medicine, Policy No. M-148

[Investigational \(Experimental\) Services, New and Emerging Medical Technologies and Procedures, and Other Non-Covered Services](#), Medicine, Policy No. M-149

[Percutaneous Neuromodulation Therapy \(PNT\) and Percutaneous Electrical Nerve Stimulation \(PENS\)](#), Surgery, Policy No. M-44

[Vagus Nerve Stimulation \(VNS\)](#), Surgery, Policy No. M-74

[Gastric Electrical Stimulation](#), Surgery, Policy No. M-111

[Sacral Nerve Stimulation \(Neuromodulation\) for Pelvic Floor Dysfunction](#), Surgery, Policy No. M-134

[Subcutaneous Tibial Nerve Stimulation](#), Surgery, Policy No. M-154

[Occipital Nerve Stimulation \(ONS\)](#), Surgery, Policy No. M-174

## REFERENCES

1. [H-Wave | Evidence Based Solution for Pain Relief & Injury Recovery](#)
2. Noridian web page for [Functional Electrical Stimulation - Coverage and HCPCS Coding – Revised](#)
3. Noridian Article for Transcutaneous Electrical Joint Stimulation Device (TEJSD) – Policy Article – Effective August 2014 (A52713) [Last Cited 08/27/2024] (*This reference can be found on the [Medicare Coverage Database](#) website*)
4. Noridian website for *Electrical Joint Stimulation Devices – E0762 – Coding Guidelines*; Available at: <https://med.noridianmedicare.com/web/jddme/article-detail/-/view/2230703/electrical-joint-stimulation-devices-e0762-coding-guidelines> [Last cited 08/27/2024]
5. Medicare Claims Processing Manual, Pub. No. 100-04, Chapter 32 – Billing Requirements for Special Services, [§11.1 – Electrical Stimulation](#)
6. Medicare Pricing, Data Analysis and Coding (PDAC) Contractor Palmetto GBA web page for *CORRECT CODING – INTERFERENTIAL CURRENT (IFC) THERAPY DEVICES*; Available at: <https://dmepdac.com/palmetto/PDACv2.nsf/DID/SXABGC79OK.com/palmetto/PDACv2.nsf/DID/SXABGC79OK> [Last cited 08/27/2024]
7. Noridian web page for *Correct Coding – Interferential Current (IFC) Therapy Devices*; Available at: <https://med.noridianmedicare.com/web/jddme/search-result/-/view/2230703/correct-coding-interferential-current-ifc-therapy-devices> [Last cited 08/27/2024]
8. Medicare Claims Processing Manual, Pub. No. 100-04, Chapter 32 – Billing Requirements for Special Services, [§11.2 – Electromagnetic Therapy](#)
9. Medicare PDAC Contractor Palmetto GBA website and *Product Classification List*; Available at: [https://www4.palmettogba.com/pdac\\_dmecs/](https://www4.palmettogba.com/pdac_dmecs/)
10. Noridian [Policy Article for External Upper Limb Tremor Stimulator Therapy](#) – Effective April 2024 (A59680)

## CODING

### NOTES:

- Electrical stimulation or electromagnetic devices and procedures which require prior authorization are found on our “*Medicare Pre-authorization List*” web page. Specific electrostimulation and/or electromagnetic codes not listed on the prior authorization website do not require prior approval. There may be additional electrical stimulation codes that are not included in this or another Medicare Advantage medical policy. However, providers are always expected to follow Medicare’s medical necessity requirements when rendering treatment to beneficiaries.
- HCPCS codes G0282 and G0295 are both Medicare Status “N” codes, and therefore, are non-covered by Medicare and Medicare Advantage.

Codes	Number	Description
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<b>CPT</b>	0278T	Transcutaneous electrical modulation pain reprocessing (eg, scrambler therapy), each treatment session (includes placement of electrodes)
	0766T	Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, with identification and marking of the treatment location, including noninvasive electroneurographic localization (nerve conduction localization), when performed; first nerve
	0767T	Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, with identification and marking of the treatment location, including noninvasive electroneurographic localization (nerve conduction localization), when performed; each additional nerve (List separately in addition to code for primary procedure)
	0768T	<del>Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, subsequent treatment, including noninvasive electroneurographic localization (nerve conduction localization), when performed; first nerve (Deleted 01/01/2024)</del>
	0769T	<del>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) (Deleted 01/01/2024)</del>
	0882T	Intraoperative therapeutic electrical stimulation of peripheral nerve to promote nerve regeneration, including lead placement and removal, upper extremity, minimum of 10 minutes; initial nerve (List separately in addition to code for primary procedure)
	0883T	Intraoperative therapeutic electrical stimulation of peripheral nerve to promote nerve regeneration, including lead placement and removal, upper extremity, minimum of 10 minutes; each additional nerve (List separately in addition to code for primary procedure)
	<b>HCPCS</b>	A4540
A4541		Monthly supplies for use of device coded at e0733
A4542		Supplies and accessories for external upper limb tremor stimulator of the peripheral nerves of the wrist
A4544		Electrode for external lower extremity nerve stimulator for restless legs syndrome
A4560		Neuromuscular electrical stimulator (nmes), disposable, replacement only
A4596		Cranial electrotherapy stimulation (ces) system supplies and accessories, per month
E0490		Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, controlled by hardware remote
E0491		Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by hardware remote, 90-day supply



E0492	Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, controlled by phone application
E0493	Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by phone application, 90-day supply
E0731	Form fitting conductive garment for delivery of TENS or NMES (with conductive fibers separated from the patient's skin by layers of fabric)
E0732	Cranial electrotherapy stimulation (ces) system, any type
E0733	Transcutaneous electrical nerve stimulator for electrical stimulation of the trigeminal nerve
E0734	External upper limb tremor stimulator of the peripheral nerves of the wrist
E0743	External lower extremity nerve stimulator for restless legs syndrome, each
E0744	Neuromuscular stimulator for scoliosis
E0745	Neuromuscular stimulator, electronic shock unit
E0761	Non-thermal pulsed high frequency radiowaves, high peak power electromagnetic energy treatment device.
E0762	Transcutaneous electrical joint stimulation device system
E0764	Functional neuromuscular stimulator, transcutaneous stimulation of muscles of ambulation with computer control, used for walking by spinal cord injured, entire system after completion of training program  <b>Note:</b> Code E0764 does not require code verification by the Medicare PDAC; however, currently the only product reported with HCPCS code E0764 is the Parastep I (Sigmedics). <sup>[3]</sup>
E0769	Electrical stimulation or electromagnetic wound treatment device, not otherwise classified
E0770	Functional electrical stimulator, transcutaneous stimulation of nerve and/or muscle groups, any type, complete system, not otherwise specified  <b>Note:</b> Manufacturers of products billed with code E0770 must have the code(s) verified by the PDAC. The only products coded with E0770 are: <ul style="list-style-type: none"> <li>• WalkAide (Innovative Neurotronics)</li> <li>• Odstock ODFS Pace FES System (Odstock Medical/Boston Brace)</li> <li>• NESS L300 and H200 devices (Bioness)<sup>[3]</sup></li> </ul>
E1399	Durable medical equipment, miscellaneous
G0281	Electrical stimulation, (unattended), to one or more areas, for chronic stage III and stage IV pressure ulcers, arterial ulcers, diabetic ulcers, and venous stasis ulcers not demonstrating measurable signs of healing after 30 days of conventional care, as part of a therapy plan of care.
G0282	Electrical stimulation, (unattended), to one or more areas, for wound care other than described in G0281 ( <i>Non-covered by Medicare</i> )
G0295	Electromagnetic stimulation, to one or more areas, for wound care other than described in G0329 or for other uses ( <i>Non-covered by Medicare</i> )
G0329	Electromagnetic therapy, to one or more areas for chronic stage III and stage IV pressure ulcers, arterial ulcers, diabetic ulcers and venous stasis

	ulcers not demonstrating measurable signs of healing after 30 days of conventional care as part of a therapy plan of care
K1002	<del>Cranial electrotherapy stimulation (CES) system, any type (Deleted 01/01/2024)</del>
K1016	<del>Transcutaneous electrical nerve stimulator for electrical stimulation of the trigeminal nerve (Deleted 01/01/2024)</del>
K1017	<del>Monthly supplies for use of device coded at K1016 (Deleted 01/01/2024)</del>
K1018	<del>External upper limb tremor stimulator of the peripheral nerves of the wrist (Deleted 01/01/2024)</del>
K1019	<del>Replacement supplies and accessories for external upper limb tremor stimulator of the peripheral nerves of the wrist (Deleted 01/01/2024)</del>
K1023	<del>Distal transcutaneous electrical nerve stimulator, stimulates peripheral nerves of the upper arm (Deleted 01/01/2024)</del>
K1029	<del>Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by phone application, 90-day supply (Deleted 01/01/2024)</del>

**\*IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.