

## MEDICAL POLICY – 1.01.507

# Electrical Stimulation Devices

BCBSA Ref. Policies: 1.01.09, 1.01.27


Effective Date: Aug. 1, 2018  
 Last Revised: July 10, 2018  
 Replaces: N/A

**RELATED MEDICAL POLICIES:**

7.01.29 Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT)  
 8.01.58 Cranial Electrotherapy Stimulation and Auricular Electrostimulation  
 8.03.01 Functional Neuromuscular Electrical Stimulation

Select a hyperlink below to be directed to that section.

[POLICY CRITERIA](#) | [DOCUMENTATION REQUIREMENTS](#) | [CODING](#)  
[RELATED INFORMATION](#) | [EVIDENCE REVIEW](#) | [REFERENCES](#) | [HISTORY](#)

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### 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 electrical signal is the same type that a nerve would send to a muscle. 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.

**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

Service	Medical Necessity
<p><b>Services eligible for reimbursement</b></p>	<p><b>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:</b></p> <ul style="list-style-type: none"> <li>• Previous casting or splinting of a limb</li> <li>• Contractures due to soft tissue scarring (eg, from burn)</li> <li>• Previous major knee surgery (eg, total knee replacement), when there is a failure to respond to physical therapy</li> <li>• Hip replacement surgery (up until the time physical therapy begins)</li> </ul> <p><b>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:</b></p> <ul style="list-style-type: none"> <li>• The treatment site is large and using a large number of standard electrodes is impractical</li> <li>• There are multiple large treatment sites on the body that make using standard electrodes impractical</li> <li>• The treatment site is hard to reach using standard electrodes and lead wires</li> <li>• The member has a skin sensitivity that precludes use of standard electrodes, adhesive tape or lead wires</li> </ul> <p><b>Note:</b> Functional neuromuscular electrical stimulators (closed loop systems) are addressed in a separate policy (see <a href="#">Related Medical Policies</a>).</p>

Service	Investigational
<p><b>Services not eligible for reimbursement</b></p>	<p><b>Neuromuscular electrical stimulators (NMES) are considered investigational for ANY other unproven indication (eg, when used for general muscle strengthening in healthy individuals, for cardiac conditioning, for the treatment of denervated muscles or idiopathic scoliosis).</b></p>



Service	Investigational
	<p data-bbox="573 247 1312 325"><b>Electrical sympathetic stimulation therapy devices are considered investigational.</b></p> <p data-bbox="573 384 1385 462"><b>Galvanic or high-voltage galvanic stimulation is considered investigational in the treatment of chronic pain.</b></p> <p data-bbox="573 520 1409 598"><b>Microcurrent electrical nerve stimulation (MENS) devices are considered investigational.</b></p> <p data-bbox="573 657 1425 903"><b>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. (HCPCS E0762).</b></p> <p data-bbox="573 961 1369 1081"><b>Transcutaneous electrical modulation pain reprocessing (TEMPR) (also called Scrambler therapy or Calmare® pain therapy) is considered investigational (CPT 0278T).</b></p>

**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



## Documentation Requirements

- 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

Code	Description
<b>CPT</b>	
0278T	Transcutaneous electrical modulation pain reprocessing (eg, scrambler therapy), each treatment session (includes placement of electrodes)
97014	Application of modality to one or more areas; electrical stimulation, unattended
<b>HCPCS</b>	
E0745	Neuromuscular stimulator, electronic shock unit
E0762	Transcutaneous electrical joint stimulation device system, includes all accessories
E1399	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.)
G0283	Electrical stimulation (unattended), to one or more areas for indication(s) other than wound care, as part of a therapy plan of care
L8679	Implantable neurostimulator, pulse generator, any type

**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

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### Background

Pulsed electrical and electromagnetic stimulation are being investigated to improve functional status and relieve pain related to osteoarthritis (OA) 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.

### *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 address 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.

## ***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 relieve pain related to osteoarthritis (OA) and rheumatoid arthritis (RA) 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 the time-varying magnetic 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. 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 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 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.



## 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. 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.

### ***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  $\geq 50\%$  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.

## **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).<sup>14</sup> Twenty-nine treatment modalities were evaluated for 4 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 4 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***

The American Academy of Orthopaedic Surgeons published guidelines on the treatment of OA of the knee in 2013.<sup>15</sup> Due to the overall inconsistent finding for electrotherapeutic modalities, the Academy 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 2012, the American College of Rheumatology published recommendations on the use of nonpharmacologic and pharmacologic therapies for OA.<sup>16</sup> The recommendations were classified as either “strong,” “conditional,” or “none.” The College issued a conditional recommendation for the use of transcutaneous electrical stimulation for the treatment of OA of the knee. This recommendation should only be considered for patients with chronic moderate or severe pain



who are candidates for total knee arthroplasty, but who are unwilling or unable to undergo the procedure due to comorbidities or concomitant use of medications that are contraindications to surgery or are advised against the procedure by a surgeon. Updated guidelines are expected in 2018.

In 2015, the College released recommendations for the treatment of rheumatoid arthritis.<sup>17</sup> All recommended treatments were pharmacologic. Use of electrical stimulation for treating rheumatoid arthritis was not addressed. Updated guidelines are expected in 2019 or early 2020.

## Medicare National Coverage

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

## Ongoing and Unpublished Clinical Trials

Currently ongoing and unpublished trials that may influence this policy are listed in [Table 1](#).

**Table 1. Summary of Key Trials**

NCT No.	Trial Name	Planned Enrollment	Completion Date
<b>Ongoing</b>			
<a href="#">NCT02436590</a> <sup>a</sup>	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	150	Dec 2018
<b>Unpublished</b>			
<a href="#">NCT01838954</a>	The Effect of Short-wave Diathermy in Patients with Osteoarthritis of the Hand: A Randomized, Double Blinded, Placebo Controlled Trial	90	Apr 2016 (unknown)

NCT: national clinical trial.

<sup>a</sup> Denotes industry-sponsored or cosponsored trial.



## Regulatory Status

- In 2017, the ActiPatch® (BioElectronics) was cleared for marketing by FDA through the 510(k) process for over-the-counter use for adjunctive treatment of plantar fasciitis of the heel and osteoarthritis of the knee. FDA product code: PQY.
- BioniCare Bio-1000™ stimulator is a device that has received U.S. Food and Drug Administration (FDA) 510(k) marketing clearances to deliver pulsed electrical stimulation for the treatment of osteoarthritis of the knee and rheumatoid arthritis of the hand. The FDA found the device to be substantially equivalent to transcutaneous electrical nerve stimulation (TENS) devices. The BioniCare system is contraindicated in patients with demand-type pacemakers and may interfere with other electronic devices.
- Calmare® Pain Therapy Medical Device is U.S. FDA 510(k)-cleared and 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/>
- The OrthoCor™ Active Knee System (OrthoCor Medical) uses pulsed electromagnetic field energy at a radio frequency of 27.12 MHz to treat pain. The OrthoCor Knee System received marketing clearance from the FDA in 2009 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 and are supplied in packets of 15. The predicate devices are the OrthoCor (K091640) and Ivivi Torino II™ (K070541).
- The SofPulse® Electroceutical™ Therapy (Endonovo Therapeutics) received marketing clearance in 2008 as short-wave diathermy devices that apply electromagnetic energy at a radio frequency of 27.12 MHz (K070541). It is indicated for adjunctive use in the palliative treatment of postoperative pain and edema in superficial soft tissue.

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## History

Date	Comments
09/10/02	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)
04/15/03	Replace Policy - Policy reviewed with references added.



Date	Comments
05/13/03	Replace Policy - Policy section revised for clarification only.
10/16/03	Replace Policy - Interferential Stimulation Devices description updated; references added. No change to policy statement.
01/13/04	Replace Policy - TMJ as investigational for TENS was added. This is consistent with TMJ policy.
06/08/04	Replace Policy - Policy reviewed; No change to policy statement.
07/13/04	Replace Policy - Description of PENS revised; information on percutaneous neuromodulation included; policy statement revised to indicate that percutaneous neuromodulation considered investigational. No change in policy statement regarding PENS.
09/01/04	Replace Policy - Policy renumbered from PR.1.01.107. No date changes.
09/14/04	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.
12/14/04	Replace Policy - Description of TENS revised; information on dementia added; reference added; Medicare policy language on TENS added. No change to policy statement.
02/08/05	Replace Policy - RS-4i Sequential Stimulator information added. No change to policy statement.
05/31/05	Update only to web - HCPCS codes added only—no other changes and not presented to MPC.
09/13/05	Replace Policy - Interferential Stimulation and PENS/ PNT added to Rationale section. References updated; no change to policy statement.
02/06/06	Codes updated - No other changes.
05/26/06	Update Scope and Disclaimer - No other changes.
07/11/06	Replace Policy - Update description to include detail of RS 4M and RS 2M muscle stimulators; no change to policy statement.
04/10/07	Cross Reference Update - No other changes.
06/12/07	Replace Policy - Policy updated with literature review; references added. No changes in policy statement. Reviewed by practicing orthopedic surgeon in May 2007.
05/13/08	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.





Date	Comments
01/13/09	Code Update - Code E0770 added, effective 1/1/09.
08/11/09	Replace Policy - Policy updated with literature search; references added. No change to policy statement.
04/13/10	Cross Reference Update - No other changes.
06/08/10	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.
06/13/11	Replace Policy - Policy updated with literature search, reference added. No change to policy statement.
01/25/12	HCPCS codes S8130 and S8131 added to policy.
01/26/12	CPT code 0278T added.
03/13/12	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.
04/17/12	Related Policies updated; 7.01.546 added to replace 7.01.25 which has been deleted.
08/24/12	Update Related Policies. Change title for 7.01.106
11/20/12	Update Related Policies. Add 8.01.58.
02/11/13	Replace policy. Removed information on cranial electrostimulation which is addressed in Medical Policy 8.01.58. Added policy statement on scrambler therapy.
12/30/13	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.
03/21/14	Update Related Policies. Delete 7.01.106 and replace with 7.01.553.
05/12/14	Annual Review. TENS policy statements and information removed. Added references 3 and 4.
06/09/14	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.
03/10/15	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



Date	Comments
	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.
04/17/15	Update Related Policies. Remove 7.01.553 and 7.01.529 as they were archived, and add 7.01.07.
01/12/16	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.
01/29/16	Minor update. Add code L8679 to coding table.
06/01/17	Annual Review, approved May 23, 2017. Put into new format. No changes to policy statement.
05/01/18	Annual Review, approved April 18, 2018. Policy updated with literature review through January 2018. References 16-23 added. Minor edits to policy statements for clarity. Otherwise, policy statements unchanged. Removed 7.01.07 from Related Policies, added 8.01.58. Removed CPT code 64550.
08/01/18	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."

**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). ©2018 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.



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Premera:

- 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)
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  - Qualified interpreters
  - Information written in other languages

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

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Civil Rights Coordinator - Complaints and Appeals  
PO Box 91102, Seattle, WA 98111  
Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357  
Email AppealsDepartmentInquiries@Premera.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 Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services  
200 Independence Avenue SW, Room 509F, HHH Building  
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)  
Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

**Getting Help in Other Languages**

**This Notice has Important Information.** This notice may have important information about your application or coverage through Premera Blue Cross. 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 800-722-1471 (TTY: 800-842-5357).

**አማርኛ (Amharic):**

ይህ ማስታወቂያ አስፈላጊ መረጃ ይዟል። ይህ ማስታወቂያ ስለ ማመልከቻዎ ወይም የ Premera Blue Cross ሽፋን አስፈላጊ መረጃ ሊኖረው ይችላል። በዚህ ማስታወቂያ ውስጥ ቁልፍ ቀዳሾች ሊኖሩ ይችላሉ። የጤና ሽፋንዎን ለመጠበቅና በአስፋፈል እርዳታ ለማግኘት በተውሰኑ የጊዜ ገደቦች እርምጃ መውሰድ ይገባዎት ይሆናል። ይህን መረጃ እንዲያገኙ እና የለምንም ክፍያ በቋንቋዎ እርዳታ እንዲያገኙ መሰብተን አለብዎት። በስልክ ቁጥር 800-722-1471 (TTY: 800-842-5357) ይደውሉ።

**العربية (Arabic):**

يحتوي هذا الإشعار على معلومات هامة. قد يحتوي هذا الإشعار على معلومات مهمة بخصوص طلبك أو التغطية التي تزيد الحصول عليها من خلال Premera Blue Cross. قد تكون هناك تواريخ مهمة في هذا الإشعار. وقد تحتاج لاتخاذ إجراء في تاريخ معينه للحفاظ على تغطيتك الصحية أو المساعدة في دفع التكاليف. يحق لك الحصول على هذه المعلومات والمساعدة بلغتك دون تكبد أية تكلفة. اتصل بـ 800-722-1471 (TTY: 800-842-5357)

**中文 (Chinese):**

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**Beeksisni kun odeeffannoo barbaachisaa qaba.** Beeksisti kun sagantaa yookan karaa Premera Blue Cross tiin tajaajila keessan ilaalchisee odeeffannoo barbaachisaa qabaachuu danda'a. Guyyaawwan murteessaa ta'an beeksisa kana keessatti ilaalaa. Tarii kaffaltiidhaan deeggaramuuf yookan tajaajila fayyaa keessaniif guyyaa dhumaa irratti wanti raawwattan jiraachuu danda'a. Kaffaltii irraa bilisa haala ta'een afaan keessaniin odeeffannoo argachuu fi deeggarsa argachuuf mirga ni qabaattu. Lakkoofsa bilbilaa 800-722-1471 (TTY: 800-842-5357) tii bilbilaa.

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**Cet avis a d'importantes informations.** Cet avis peut avoir d'importantes informations sur votre demande ou la couverture par l'intermédiaire de Premera Blue Cross. Le présent avis peut contenir des dates clés. Vous devez peut-être prendre des mesures par certains délais pour maintenir votre couverture de santé ou d'aide avec les coûts. Vous avez le droit d'obtenir cette information et de l'aide dans votre langue à aucun coût. Appelez le 800-722-1471 (TTY: 800-842-5357).

**Kreyòl ayisyen (Creole):**

**Avi sila a gen Enfòmasyon Enpòtan ladann.** Avi sila a kapab genyen enfòmasyon enpòtan konsènan aplikasyon w lan oswa konsènan kouvèti asirans lan atravè Premera Blue Cross. Kapab genyen dat ki enpòtan nan avi sila a. Ou ka gen pou pran kèk aksyon avan sèten dat limit pou ka kenbe kouvèti asirans sante w la oswa pou yo ka ede w avèk depans yo. Se dwa w pou resewva enfòmasyon sa a ak asistans nan lang ou pale a, san ou pa gen pou peye pou sa. Rele nan 800-722-1471 (TTY: 800-842-5357).

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**ລາວ (Lao):**

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**ភាសាខ្មែរ (Khmer):**

សេចក្តីជូនដំណឹងនេះមានព័ត៌មានយ៉ាងសំខាន់។ សេចក្តីជូនដំណឹងនេះប្រហែលជាមានព័ត៌មានយ៉ាងសំខាន់អំពីទម្រង់បែបបទ ឬការរៀបចំរបស់អ្នកកាមរយ: Premera Blue Cross ។ ប្រហែលជាមាន កាលបរិច្ឆេទសំខាន់នៅក្នុងសេចក្តីជូនដំណឹងនេះ។ អ្នកប្រហែលជាត្រូវការបញ្ជាក់សមត្ថភាព ដល់កិច្ចការផ្ទៃក្នុងដូចជា ឆ្លើយតបនឹងសំណួរ ឬការបញ្ជាក់ការបំពេញតាមការបញ្ជាក់របស់អ្នក ឬប្រាក់ជំនួយចេញថ្លៃ។ អ្នកមានសិទ្ធិទទួលបានព័ត៌មាននេះ និងជំនួយនៅក្នុងភាសារបស់អ្នកដោយមិនអស់លុយឡើយ។ សូមទូរស័ព្ទ 800-722-1471 (TTY: 800-842-5357)។

**ਪੰਜਾਬੀ (Punjabi):**

ਇਸ ਨੋਟਿਸ ਵਿਚ ਖਾਸ ਜਾਣਕਾਰੀ ਹੈ. ਇਸ ਨੋਟਿਸ ਵਿਚ Premera Blue Cross ਵਲੋਂ ਤੁਹਾਡੀ ਕਵਰੇਜ ਅਤੇ ਅਰਜੀ ਬਾਰੇ ਮਹੱਤਵਪੂਰਨ ਜਾਣਕਾਰੀ ਹੋ ਸਕਦੀ ਹੈ . ਇਸ ਨੋਟਿਸ ਨਵ ਖਾਸ ਤਾਰੀਖਾਂ ਹੋ ਸਕਦੀਆਂ ਹਨ. ਜੇਕਰ ਤੁਸੀਂ ਜਸਰਤ ਕਵਰੇਜ ਰਿੱਖਣੀ ਹੋਵੇ ਜਾਂ ਓਸ ਦੀ ਲਾਗਤ ਜਵਿੱਚ ਮਦਦ ਦੇ ਇਕੱਠ ਹੋ ਤਾਂ ਤੁਹਾਨੂੰ ਅੰਤਮ ਤਾਰੀਖ ਤੋਂ ਪਹਿਲਾਂ ਢੁੱਝ ਖਾਸ ਕਦਮ ਚੁੱਕਣ ਦੀ ਲੋੜ ਹੋ ਸਕਦੀ ਹੈ ,ਤੁਹਾਨੂੰ ਮੁਫਤ ਵਿੱਚ ਤੋਂ ਅਪਣੀ ਭਾਸ਼ਾ ਵਿੱਚ ਜਾਣਕਾਰੀ ਅਤੇ ਮਦਦ ਪ੍ਰਾਪਤ ਕਰਨ ਦਾ ਅਧਿਕਾਰ ਹੈ ,ਕਾਲ 800-722-1471 (TTY: 800-842-5357).

**فارسی (Farsi):**

این اعلامیه حاوی اطلاعات مهم میباشد. این اعلامیه ممکن است حاوی اطلاعات مهم درباره فرم تقاضا و یا پوشش بیمه ای شما از طریق Premera Blue Cross باشد. به تاریخ های مهم در این اعلامیه توجه نمایید. شما ممکن است برای حفظ پوشش بیمه تان یا کمک در پرداخت هزینه های درمانی تان، به تاریخ های مشخصی برای انجام کارهای خاصی احتیاج داشته باشید. شما حق این را دارید که این اطلاعات و کمک را به زبان خود به طور رایگان دریافت نمایید. برای کسب اطلاعات با شماره 800-722-1471 (کلیران TTY تماس باشماره 800-842-5357) تماس برقرار نمایید.

**Polskie (Polish):**

To ogłoszenie może zawierać ważne informacje. To ogłoszenie może zawierać ważne informacje odnośnie Państwa wniosku lub zakresu świadczeń poprzez Premera Blue Cross. Prosimy zwrócić uwagę na kluczowe daty, które mogą być zawarte w tym ogłoszeniu aby nie przekroczyć terminów w przypadku utrzymania polisy ubezpieczeniowej lub pomocy związanej z kosztami. Macie Państwo prawo do bezpłatnej informacji we własnym języku. Zadzwońcie pod 800-722-1471 (TTY: 800-842-5357).

**Português (Portuguese):**

Este aviso contém informações importantes. Este aviso poderá conter informações importantes a respeito de sua aplicação ou cobertura por meio do Premera Blue Cross. Poderão existir datas importantes neste aviso. Talvez seja necessário que você tome providências dentro de determinados prazos para manter sua cobertura de saúde ou ajuda de custos. Você tem o direito de obter esta informação e ajuda em seu idioma e sem custos. Ligue para 800-722-1471 (TTY: 800-842-5357).

**Română (Romanian):**

Prezenta notificare conține informații importante. Această notificare poate conține informații importante privind cererea sau acoperirea asigurării dumneavoastră de sănătate prin Premera Blue Cross. Pot exista date cheie în această notificare. Este posibil să fie nevoie să acționați până la anumite termene limită pentru a vă menține acoperirea asigurării de sănătate sau asistența provizorie la costuri. Aveți dreptul de a obține gratuit aceste informații și ajutor în limba dumneavoastră. Sunați la 800-722-1471 (TTY: 800-842-5357).

**Русский (Russian):**

Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть указаны ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).

**Fa'asamoa (Samoan):**

Atonu ua iai i lenei fa'asilasilaga ni fa'amatalaga e sili ona taua e tatau ona e malamalama i ai. O lenei fa'asilasilaga o se fesoasoani e fa'amatala atili i ai i le tulaga o le polokalame, Premera Blue Cross, ua e tau fia maua atu i ai. Fa'amolemole, ia e iloilo fa'alelei i aso fa'apitoa olo'o iai i lenei fa'asilasilaga taua. Masalo o le'a iai ni feau e tatau ona e faia ao le'i aulia le aso ua ta'ua i lenei fa'asilasilaga ina ia e iai pea ma maua fesoasoani mai ai i le polokalame a le Malo olo'o e iai i ai. Olo'o iai iate oe le aia tatau e maua atu i lenei fa'asilasilaga ma lenei fa'matalaga i legagana e te malamalama i ai aunoa ma se togiga tupe. Vili atu i le telefoni 800-722-1471 (TTY: 800-842-5357).

**Español (Spanish):**

Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. 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 800-722-1471 (TTY: 800-842-5357).

**Tagalog (Tagalog):**

Ang Paunawa na ito ay naglalaman ng mahalagang impormasyon tungkol sa iyong aplikasyon o pagsakop sa pamamagitan ng Premera Blue Cross. Maaaring may mga mahalagang petsa dito sa paunawa. Maaring mangailangan ka na magsagawa ng hakbang sa ilang mga itinakdang panahon upang mapanatili ang iyong pagsakop sa kalusugan o tulong na walang gastos. May karapatan ka na makakuha ng ganiitong impormasyon at tulong sa iyong wika ng walang gastos. Tumawag sa 800-722-1471 (TTY: 800-842-5357).

**ไทย (Thai):**

ประกาศนี้มีข้อมูลสำคัญ ประกาศนี้อาจมีข้อมูลที่สำคัญเกี่ยวกับกาการสมัครหรือขอบเขตประกันสุขภาพของคุณผ่าน Premera Blue Cross และอาจมีกำหนดการในประกาศนี้ คุณอาจจะต้องดำเนินการภายในกำหนดระยะเวลาที่แน่นอนเพื่อจะรักษาการประกันสุขภาพของคุณหรือการช่วยเหลือที่มีค่าใช้จ่าย คุณมีสิทธิที่จะได้รับข้อมูลและความช่วยเหลือในภาษาของคุณโดยไม่มีค่าใช้จ่าย โทร 800-722-1471 (TTY: 800-842-5357)

**Український (Ukrainian):**

Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо страховального покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути вказані у цьому повідомленні. Існує імовірність того, що Вам треба буде здійснити певні кроки у конкретні кінцеві 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. Дзвоніть за номером телефону 800-722-1471 (TTY: 800-842-5357).

**Tiếng Việt (Vietnamese):**

Thông báo này cung cấp thông tin quan trọng. Thông báo này có thông tin quan trọng về đơn xin tham gia hoặc hợp đồng bảo hiểm của quý vị qua chương trình Premera Blue Cross. Xin xem ngày quan trọng trong thông báo này. Quý vị có thể phải thực hiện theo thông báo đúng trong thời hạn để duy trì bảo hiểm sức khỏe hoặc được trợ giúp thêm về chi phí. Quý vị có quyền được biết thông tin này và được trợ giúp bằng ngôn ngữ của mình miễn phí. Xin gọi số 800-722-1471 (TTY: 800-842-5357).