I. DESCRIPTION/BACKGROUND

H-wave Electrical Stimulation

H-wave electrical stimulation is a form of electrical stimulation that differs from other forms of electrical stimulation, such as transcutaneous electrical nerve stimulation (TENS) in terms of waveform. 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 dysfunction, reflex sympathetic dystrophy or to accelerate the healing process of wounds such as diabetic ulcers. This form of stimulation can be performed by physiatrists, chiropractors or podiatrists, and is also available for home use.

Note: H-wave electrical stimulation must be distinguished from the H-Waves that are a component of electromyography.

A variety of devices may be used for H-wave stimulation. In general, the U.S. Food and Drug Administration (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.”

High Voltage Galvanic Stimulation (HVG)

High voltage galvanic stimulation (HVG) uses high voltage, pulse stimulation to reduce local edema, relax muscle spasms, increase local blood circulation, maintain or increase range of motion, prevent or retard disuse atrophy, conduct muscle re-education, and affect immediate post-surgical stimulation of calf-muscles to prevent thrombosis. The High Voltage Galvanic Stimulator (Control Solutions, Inc.) was 501(k) approved by the U.S. Food and Drug Administration (FDA) in June, 2004.

Horizontal Therapy

Horizontal therapy is a type of electrotherapy used in the treatment of osteoarthritis, with low frequency, variable intensity stimulatory frequencies and non-stimulatory, medium frequency alternating current therapies.
### Interferential Stimulation

Interferential stimulation is a type of electrical stimulation that uses paired electrodes of two (2) independent circuits carrying medium-frequency alternating currents. The electrodes are aligned on the skin so that the current permeates the tissues at a target, thus maximizing the current entering the tissues while reducing the unwanted stimulation of the cutaneous nerves. Interferential stimulation has been investigated as a procedure to reduce pain, improve range of motion and promote healing following a tissue injury. There are no standard protocols for use of interferential stimulation. This therapy may vary according to frequency of stimulation, the duration, treatment time and electrode placement.

RS Medical's sequential stimulation therapy (i.e., RS-4i Sequential Stimulator®) treats patients with painful muscle conditions. Sequential stimulation first uses interferential current to relieve pain, then applies muscle stimulation to treat underlying muscle conditions.

### Neuromuscular Electrical Stimulation (NMES)

Neuromuscular electrical stimulation (NMES) involves the use of devices that transmit electrical impulses through electrodes to stimulate muscle groups. There are two different types of NMES: one is functional electrical stimulation (FES) and the second is lateral electrical surface stimulation (LESS).

Functional electrical stimulation (FES) attempts to replace stimuli from destroyed nerve pathways with sequential electrical stimulation of muscles to enable spinal cord injured patients to stand or walk independently, or to maintain healthy muscle tone and strength. Usually, only patients with injury from the fourth to the twelfth thoracic (T-4 to T-12) vertebrae are candidates for FES. FES technologies differ in the manner in which the electrodes are placed, either implanted, placed transcutaneously, or percutaneously. To date, the Parastep® is the only FES neuromuscular stimulation device that has been approved by the U.S. Food and Drug Administration (FDA) to provide ambulation. Using percutaneous stimulation, the Parastep® device delivers trains of electrical impulses to trigger action at selected nerves at the quadriceps (for knee extension), the common peroneal nerve (for hip flexion), and the paraspinals and gluteals (for trunk stability). Patients use a walker or elbow support crutches for further support. The electrical impulses are controlled by a computer microchip attached to the patient’s belt that synchronizes and distributes the signals. In addition, there is a finger-controlled switch that the patient can activate for stepping.

Lateral electrical stimulation (LESS) is used to treat patients with disuse atrophy of the muscles where the nerve supply to the muscle is intact. This treatment is used in assisting a patient’s recovery and functional improvement following surgery or certain illnesses.
Percutaneous Electrical Neurostimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT)

Percutaneous electrical nerve stimulation (PENS) is used to relieve pain and is essentially the same as transcutaneous electrical nerve stimulation (TENS) except that, unlike TENS, the stimulating electrodes are surgically implanted around, or immediately adjacent to, the nerve serving the painful area. The insulated leads are connected to a receiver unit that is under the skin. Stimulation is induced by a generator, which is placed on the skin surface over the receiver unit. This is not to be confused with electroacupuncture or TENS acupuncture.

Percutaneous neuromodulation therapy is a modality developed for treatment of chronic intractable low back pain by delivering electrical stimulation percutaneously to the deep tissues near the spine.

Premodulated Electrical Stimulation

Most interferential stimulation units in use today also have the capacity to produce a "premodulated" electrical current. The amplitude of the single channel that is used is altered to produce a current that is similar to the beat frequency produced by true interferential current. But premodulated electrical stimulation operates similarly to transcutaneous electrical nerve stimulation because the units cannot produce the same field effects as when the two channels in interferential cross.

Transcutaneous Electrical Nerve Stimulator (TENS)

Transcutaneous electrical nerve stimulator (TENS) is an electronic device that applies electrical stimulation to the skin surface at the pain site. The device is used to relieve chronic intractable pain, post-surgical pain, or pain associated with traumatic injury unresponsive to other standard pain management therapies. TENS units may be used in an inpatient, outpatient or home setting.

Typically, TENS units are prescribed for a trial period no more than two months in duration. During the trial period, a physician, physical therapist, or chiropractor monitors the patient to evaluate the effectiveness of the device in the management of the patient’s pain.

The BioniCare BIO-1000 stimulator, recently cleared for marketing by the U.S. Food and Drug Administration (FDA), functions as a type of transcutaneous electrical nerve stimulation (TENS) device for use in osteoarthritis of the knee and rheumatoid arthritis of the hand. The BioniCare system consists of an electronic stimulator device with electrical leads that are placed over the affected area and held in place with a lightweight, flexible wrap and Velcro fasteners. The battery-powered device delivers small electrical currents of 0.0 to 12.0 volt output.
Transcutaneous Transducer Garment

Transcutaneous electrical nerve stimulation (TENS) or neuromuscular electrical stimulation (NMES) is usually delivered to patients through the use of electrodes applied to the skin surface. There may be times, however, when certain patients receive TENS or NMES treatment using a garment with conductive fibers that are separated from the patient’s skin by layers of fabric. The conductive garment is worn as an alternative to the conventional TENS/NMES unit.

Threshold Electrical Stimulation

A threshold electrical stimulation device is used to deliver low intensity electrical stimulation to spastic muscles during sleep. Although the mechanism of action is not clearly understood, it is believed that low intensity stimulation may increase muscle strength and joint mobility causing improvement in voluntary motor function. However, the stimulation is not intended to cause muscle contraction. This type of treatment has been used extensively in children with spastic diplegia related to cerebral palsy and in the treatment of other motor disorders, such as spina bifida.

II. Definitions

510 (k) is a premarketing submission made to the U.S. Federal Drug Administration to demonstrate that the device to be marketed is as safe and effective as, that is, substantially equivalent (SE) to, a legally marketed device that is not subject to premarket approval (PMA). Applicants must compare their 510(k) device to one or more similar devices currently on the U.S. market and make and support their substantial equivalency claims.

Percutaneous refers to that which is passed or effected through the skin.

Premodulated Electrical Stimulation refers to a form of interferential electrical stimulation that only requires the use of one circuit, with the current modulated within the machine to accomplish the change in intensity.

Spastic Diplegia describes excessive spastic stiffness in the limbs.

Transcutaneous refers to a procedure that is performed through the skin.

Transcutaneous Electrical Nerve Stimulator (TENS) is an electronic device that applies electrical stimulation to the skin surface at the pain site. The device is used to relieve chronic intractable pain, post-surgical pain, or pain associated with traumatic injury unresponsive to other standard pain management therapies. TENS units may be used in an inpatient, outpatient or home setting.
Typically, TENS units are prescribed for a trial period no more than two months in duration. During the trial period, a physician or physical therapist monitors the patient to evaluate the effectiveness of the device in the management of the patient’s pain.

### III. Policy

**Lateral Neuromuscular Electrical Stimulation (LESS)**

Lateral neuromuscular electrical stimulation (LESS/NMES) may be considered medically necessary to treat muscle atrophy where the nerve supply to the muscle is intact, including brain, spinal cord, and peripheral nerves, and the patient has one or more of the following non-neurological reasons for disuse atrophy:

- Previous casting or splinting of a limb;
- Contractures due to scarring from burns;
- Recent hip replacement surgery (until physical therapy begins); or
- Previous major knee surgery (when there is failure to respond to physical therapy).

A home unit for NMES may be considered medically necessary after a successful trial period with a rental unit for the above situations, such as the RS Medical RS-4m Muscle Stimulation unit.

**Percutaneous Electrical Neurostimulation (PENS)**

Percutaneous electrical nerve stimulation (PENS) is considered medically necessary and appropriate when prescribed for a trial period not exceeding two months as:

- A treatment or modality on an inpatient or outpatient basis, or at home; and
- Is used to relieve chronic intractable pain under the supervision of a physician or physical therapist; and
- Used in conjunction with a physical therapy program.

PENS is considered medically necessary for continued use beyond a trial period of two months in the presence of documentation substantiating the effectiveness of the PENS in significantly reducing the patient’s symptoms.

Individual consideration may be given to the purchase of PENS units (in lieu of rental) used to treat long-term or chronic pain conditions.

**Transcutaneous Electrical Nerve Stimulator (TENS)**
## ELECTRICAL STIMULATION MODALITIES

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<th>POLICY TITLE</th>
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<td>Transcutaneous Transducer Garment</td>
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Refer to 2006 InterQual Criteria Subset: Transcutaneous Electrical Nerve Stimulation (TENS): General and Senior

**Transcutaneous Transducer Garment**

The form-fitting conductive garment may be considered **medically necessary** when **all** of the following criteria are met:

- The garment has received permission or approval for marketing by the U.S. Food and Drug Administration;
- The garment has been prescribed by a physician for use in delivering covered TENS treatment; and
- The garment is prescribed for one of the medical indications outlined below:
  - The area to be stimulated is so large or there are so many sites to be stimulated and the stimulation would have to be delivered so frequently that it is not feasible to use electrodes, adhesive tapes, and lead wires;
  - The areas or sites to be stimulated are inaccessible with the use of electrodes, adhesive tape, and lead wires;
  - There is documentation of a medical condition such as skin problems that preclude the application of electrodes, adhesive tape and lead wires;

**Cross-references**

- MP-1.042 Deep Brain Stimulation
- MP-1.069 Dorsal Column Stimulator
- MP-1.024 Electrical Bone Growth Stimulation
- MP-6.035 Electrostimulation and Electromagnetic Therapy for Chronic Wounds
- MP-2.069 Gastric Electrical Stimulation
- MP-1.034 Implantable Nerve Stimulators (Vagus, Autonomic Nerve, and Peripheral Nerve Stimulators)
- MP-2.029 Neurofeedback
- MP-6.024 Pelvic Floor Stimulation Device
- MP-1.033 Sacral Nerve Stimulation for Urinary Incontinence
- MP-1.077 Stimulation of the Sacral Anterior Root Combined with Posterior Sacral Rhizotomy in Patients with Spinal Cord Injury
- MP-6.033 Sympathetic Therapy for the Treatment of Pain
- MP-6.019 Threshold Electrical Stimulation Device
IV. EXCLUSIONS

Functional Electrical Stimulation (FES)

Functional electrical stimulation (FES) to provide ambulation in spinal cord injured patients or treat other insults to the central or peripheral nervous systems is considered investigational, as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

In addition, lateral neuromuscular electrical stimulation (LESS/NMES) is considered not medically necessary for the treatment of muscle pain, tension headaches, or other chronic pain syndromes.

All forms of neurofeedback, including EMG-controlled neuromuscular electrical stimulation (i.e., the AutoMove™ AM800 or Care EMG™) are considered investigational, as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

H-wave Electrical Stimulation

H-wave stimulation is considered investigational, as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

High Voltage Galvanic Stimulation (HVG)

High voltage galvanic stimulation (HVG) is considered investigational, as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Horizontal Therapy

Horizontal therapy is considered investigational, as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Interferential Stimulation and Sequential Stimulation

Interferential current stimulation and sequential stimulation (i.e., RS Medical's RS-4i® Sequential Stimulator) are considered investigational, as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.
Percutaneous Electrical Neurostimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT)

Percutaneous neuromodulation therapy is considered investigational, as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Percutaneous electrical nerve stimulation used for conditions other than listed above is considered investigational, as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Premodulated Electrical Stimulation

Premodulated electrical stimulation is considered investigational, as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Transcutaneous Electrical Nerve Stimulator (TENS)

Transcutaneous electrical nerve stimulator (TENS) used for treatment of conditions other than chronic intractable pain or immediate post-operative pain is considered investigational, including use for low back pain. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this treatment.

The BioniCare BIO-1000 stimulator is considered investigational, as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Threshold Electrical Stimulation

Threshold electrical stimulation as a treatment of motor disorders including, but not limited to, cerebral palsy, is considered investigational, as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

V. Benefit Variations

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member’s individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member’s benefit information or contact Capital for benefit information.
VI. DISCLAIMER

Capital’s medical policies are developed to assist in administering a member’s benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member’s benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VII. REFERENCES

**H-wave Electrical Stimulation**


BCBSA 1996 TEC Assessments, Tab 21.

Johnson MI. Transcutaneous electrical nerve stimulation (TENS) and TENS-like devices: do they provide pain relief? Pain Reviews 2001; 8:121-158.


Taber’s Cyclopedic Medical Dictionary, 19th edition.

**High Voltage Galvanic Stimulation (HVG)**


**MEDICAL POLICY**

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**Horizontal Therapy**


**Interferential Stimulation**


**Neuromuscular Electrical Stimulation (NMES)**


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Taber’s Cyclopedic Medical Dictionary, 19th edition.

**Percutaneous Electrical Neurostimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT)**


BCBSA 1996 TEC Assessments, Tab 21.


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Taber’s Cyclopedic Medical Dictionary, 19th edition.


Threshold Electrical Stimulation


Taber’s Cyclopedic Medical Dictionary, 19th edition.

### VIII. PRODUCT VARIATIONS

[N] = No product variation, policy applies as stated  
[Y] = Standard product coverage varies from application of this policy, see below

| [N] CHIP PPO | [N] Indemnity |
| [N] PPO | [N] SpecialCare |
| [N] HMO | [N] POS |
| [N] CHIP HMO | [Y] FEP HMO* |
| [Y] SeniorBlue** | [Y] FEP PPO* |
| [Y] SeniorBlue PPO** |

* The FEP program dictates that all devices approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational. Therefore, FDA-approved devices may be assessed on the basis of medical necessity.

** For coverage information:

2. For neuromuscular electrical stimulation (NMES)/functional electrical stimulation (FES) in the treatment of disuse atrophy, used for assisting patients with spinal cord injuries (SCI) to walk: Medicare National Coverage Determination Manual, Chapter 1, Part 2, 150.4.