

MEDICAL POLICY

SUBJECT: ELECTRICAL STIMULATION: TRANSCUTANEOUS ELECTRICAL NERVE (TENS), PERCUTANEOUS ELECTRICAL NERVE (PENS), H-WAVE and INTERFERENTIAL STIMULATORS	EFFECTIVE DATE: 03/06/02 REVISED DATE: 03/27/03, 04/22/04, 04/28/05, 06/22/06, 06/28/07, 06/26/08, 06/25/09, 06/24/10, 06/24/11, 10/25/12, 06/27/13, 10/24/13, 08/28/14, 06/25/15, 06/22/16, 06/22/17, 06/28/18
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<ul style="list-style-type: none">• <i>If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</i>• <i>If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.</i>• <i>If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.</i>	

POLICY STATEMENT:

- I. Based upon our criteria and review of the peer-reviewed literature, *TENS*, including the BioniCare® Stimulator Model BIO-1000™, and *H-wave Stimulation* have been medically proven to be effective and therefore **medically appropriate** for pain when:
 - A. symptoms have persisted greater than three months; and
 - B. failure of physical therapy, osteopathic manipulative therapy, or chiropractic therapy; and
 - C. failure of medications (e.g., simple analgesics, nonsteroidal anti-inflammatory drugs [NSAIDS], or opioids); and
 - D. the efficacy of TENS or H-Wave Stimulator for the individual patient has been established up to a one month trial period.
- II. Based upon our criteria and review of the peer-reviewed literature, *TENS* or *H-wave stimulation* do not improve patient outcomes and are **not medically necessary** for the following indications:
 - A. the relief of pain in labor and vaginal delivery;
 - B. treatment of headaches;
 - C. visceral abdominal pain;
 - D. temporomandibular joint (TMJ) disorder;
 - E. cancer pain;
 - F. low back pain; or
 - G. neck pain.
- III. Based upon our criteria and review of the peer-reviewed literature, the BioniCare® Stimulator Model BIO-1000™ has not been proven to facilitate the repair of cartilage in patients with arthritis and is considered **investigational** for this indication.
- IV. Based upon our criteria and review of the peer-reviewed literature, PENS and PNT have not been proven to be medically effective and are considered **investigational**.
- V. Based upon our criteria and review of the peer-reviewed literature, *interferential stimulation* (e.g. RS-4i® Sequential Stimulator, RS Medical, Empi IF 3WAVE®, DJO Global) has not been proven to be medically effective and is considered **investigational**.
- VI. Based upon our criteria and review of the peer-reviewed literature, TENS devices capable of delivering three separate modalities such as interferential stimulation, electrical stimulation and neuromuscular electrical stimulation (e.g., TruWave™ Plus, Zynex Medical, NexWave™, Zynex Medical, Empi Continuum™, DJO Global) are considered **investigational**.
- VII. Based upon our criteria and review of the peer-reviewed literature, the Cefaly® device has not been proven to be medically effective for the treatment of migraine headaches and is considered **investigational** for this indication.
- VIII. The use of TENS therapy is a relative **contraindication** in patients with a pacemaker or an implantable cardioverter defibrillator (ICD). Electrical interference from the TENS unit has been reported and may interfere with the proper function of these devices.

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Refer to Corporate Medical Policy #1.01.19 regarding Pelvic Floor Electrical Stimulation as a Treatment for Urinary or Fecal Incontinence.

Refer to Corporate Medical Policy #1.01.48 regarding Neuromuscular Stimulation.

POLICY GUIDELINES:

- I. Durable Medical Equipment rider/coverage required.
- II. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

- I. **Transcutaneous Electrical Nerve Stimulation (TENS)** is the application of an electrical current through the skin to stimulate the nervous system. The electronic device is attached to the surface of the skin over the peripheral nerve to be stimulated and is used to relieve chronic intractable pain, post-operative pain and pain associated with active or post-trauma injury unresponsive to other standard pain therapies. TENS consists of an electrical pulse generator, usually battery operated, connected by wire to two or more electrodes which are applied to the surface of the skin at the site of the pain. The BioniCare® Stimulator Model BIO-1000TM is classified as a TENS unit by the FDA.
- II. **Percutaneous Electrical Nerve Stimulation (PENS)** is a similar concept to TENS but different in that needles are inserted around or adjacent to the nerve serving the painful stimuli and then stimulated. PENS is generally reserved for patients who fail to get pain relief from TENS. Percutaneous neuromodulation therapy (PNT) is a variant of PENS in which the needles are inserted at specific anatomical landmarks on the back.
- III. **H-wave stimulation** is a form of electrical stimulation that differs from other forms of stimulation in terms of its waveform. H-wave devices are available for home use as durable medical equipment. H-wave stimulation has been used for pain control, treatment of diabetic neuropathy, muscle sprains, temporomandibular joint dysfunctions or reflex sympathetic dystrophy. It has also been used to accelerate healing of wounds (e.g., diabetic ulcers).
- IV. **Interferential stimulation** is an anti-inflammatory based treatment modality. The interferential stimulator crosses two medium frequency alternating currents, which penetrate deep into soft tissue. It is used in the treatment of circulation disorders, range of motion, edema and muscle spasms. It is reported to stimulate bone healing, inhibit pain and promote soft tissue healing.
- V. **Combination transcutaneous electrical nerve stimulation, interferential stimulation and neuromuscular electrical stimulation** is a TENS device capable of delivering any of the three modalities depending on electrode arrangement on the body and programming options. This device is used to treat a wide variety of symptoms especially for acute and chronic pain relief. The TruWave™Plus is an example of this type of device.
- VI. **Transcutaneous electrical nerve stimulation for treatment and prevention of migraines.** The Cefaly® device received FDA approval on March 11, 2014 for treatment of migraines in patients aged 18 years and older. Cefaly is a small, portable, battery-powered, prescription device that resembles a plastic headband worn across the forehead and atop the ears. The user positions the device in the center of the forehead, just above the eyes, using a self-adhesive electrode. The device applies an electric current to the skin and underlying body tissues to stimulate branches of the trigeminal nerve, which has been associated with migraine headaches. The user may feel a tingling or massaging sensation where the electrode is applied. The device should only be worn daily for 20 minutes.

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RATIONALE:

A number of interferential stimulator devices have received FDA approval including the Medstar 100® (Mednet Services and the RS-4V® (RS Medical). The FDA approved the BioniCare® Stimulator Model BIO-1000™ in 1997 for use as an adjunctive therapy in reducing the level of pain and symptoms associated with osteoarthritis of the knee and in 1999 as adjunct therapy for reducing the level of pain and stiffness associated with osteoarthritis of the hand.

TENS and H Wave Muscle Stimulators have a treatment effect beyond that of a credible placebo. Their use may be justified in those individuals with mild acute or chronic pain who wish to use a nonpharmacological form of analgesia. Published clinical trials have not provided evidence to support the efficacy of interferential stimulation compared to current treatment options. An abstract of 101 patients presented at the 2004 annual meeting of the American Academy of Orthopaedic Surgeons reported that 50% of patients avoided total knee arthroplasty by using the BioniCare® system. However, there was no randomly assigned control group in this abstract. The FDA classified this device as a TENS unit, however the manufacturer has indicated it is a new category of device since it uses a different array of proprietary electrical amplitudes than a TENS unit and does not function to stimulate nerves. Instead, the BioniCare® device is purported to stimulate chondrogenesis. However, no studies have been performed to evaluate whether chondrogenesis occurs with use of this device.

Recently CMS has posted a Decision Memo for Transcutaneous Electrical Nerve Stimulation for Chronic Low Back Pain. Chronic low back pain is defined as an episode of low back pain that has persisted for three months or longer; and is not a manifestation of a clearly defined and generally recognizable primary disease entity (e.g., cancers that, through metastatic spread to the spine or pelvis. rheumatoid arthritis and multiple sclerosis). The memo states that TENS is not reasonable and necessary for the treatment of chronic low back pain. In order to support additional research on the use of TENS for chronic low back pain, CMS will cover TENS when the member is enrolled in an approved clinical study meeting all of the requirements listed in the Decision Memo. Case reports have indicated that a transcutaneous electrical nerve stimulator (TENS) has been known to interfere with an implantable cardioverter defibrillator (ICD) and pacemakers.

The peer-reviewed literature concerning PENS and PNT consist of small, single center, randomized control trials. The studies do not address long-term improvement of pain and functional outcomes. There is no evidence about the adverse effects of PENS and PNT or their acceptability over repeated courses of therapy. Therefore, the available evidence does not permit conclusions about the long-term effectiveness of PENS and PNT.

The peer-review literature concerning the use of transcutaneous electrical nerve stimulation for the treatment of migraine headaches consists of results from the Prevention of Migraine (PREMICE) trial of 67 patients randomized to receive the Cefaly® device or sham treatment daily for 20 minutes for 3 months. After the first month of treatment both the treatment and sham group showed a decrease in migraine days by an average of 20%. This decrease disappeared in the sham group by the 2nd and 3rd month but continued in the treatment group. The 50% responder rate was greater in the treatment group and the therapeutic gain of effective stimulation over sham was 26%. The monthly attack frequency from the 1st to the 3rd month was reduced by 18.8% in the treatment group and by only 3.5% in the sham group. Headache severity and the monthly intake of anti-migraine medications was also reduced in the treatment group. No adverse events or side effects were found for either the treatment or sham group. Compliance was moderately satisfactory in both groups. The responder rate for electrical stimulation was within the range of those reported for other migraine treatment modalities. However the study size was small and the selected cohort were not severely disabled by their migraines.

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CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

<u>CPT:</u>	64550	Application of surface (transcutaneous) neurostimulator
	64555	Percutaneous implantation of neurostimulator electrodes; peripheral nerve (excludes sacral nerve)
	97014	Application of a modality to one or more areas; electrical stimulation, unattended
	97032	Application of a modality to one or more areas; electrical stimulation (manual), each 15 minutes

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<u>HCPCS:</u>	A4595	Electrical stimulation supplies, 2 lead, per month, (e.g., TENS, NMES)
	A4630	Replacement batteries , medically necessary, transcutaneous electrical stimulator, owned by patient
	E0720	TENS, two lead, localized stimulation
	E0730	TENS, four or more leads, for multiple nerve stimulation
	E0731	Form-fitting conductive garment for delivery of TENS or NMES (with conductive fibers separated from the patient's skin by layers of fabric).

The following HCPCS code is considered investigational if not used as a TENS device:

E0762	Transcutaneous electrical joint stimulation device system, includes all accessories
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The following HCPCS codes are considered investigational:

S8130	Interferential current stimulator, 2 channel
S8131	Interferential current stimulator, 4 channel

<u>ICD10:</u>	E08.40-E08.42	Diabetes mellitus due to underlying condition with diabetic neuropathy (code range)
	E09.40-E09.42	Drug or chemical induced diabetes mellitus with neurological complications with diabetic neuropathy (code range)
	E10.40-E10.42	Type 1 diabetes mellitus with diabetic neuropathy (code range)
	E11.40-E11.42	Type 2 diabetes mellitus with diabetic neuropathy (code range)
	E13.40-E13.42	Other specified diabetes mellitus with diabetic neuropathy (code range)
	G13.0-G13.1	Paraneoplastic neuromyopathy and neuropathy (code range)
	G43.0-G43.91	Migraine (code range)
	G44.0-G44.89	Other headache syndromes (code range)

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G54.8	Other nerve root and plexus disorders
G55	Nerve root and plexus compressions in diseases classified elsewhere
G56.00-G56.92	Carpal tunnel syndrome, upper limb (code range)
G57.00-G57.92	Lesion of sciatic nerve, lower limb (code range)
G58.0-G59	Mononeuropathy (code range)
G63	Polyneuropathy in diseases classified elsewhere
G65.0-G65.2	Sequelae of inflammatory polyneuropathy (code range)
G90.50-G90.59	Complex regional pain syndrome I (code range)
M15.0-M15.9	Primary generalized osteoarthritis (code range)
M16.0-M16.9	Osteoarthritis of hip (code range)
M17.0-M17.9	Osteoarthritis of knee (code range)
M18.0-M18.9	Osteoarthritis of carpometacarpal joints (code range)
M19.011-19.93	Osteoarthritis, shoulder, arm and hand (code range)
M34.83	Systemic sclerosis with polyneuropathy
M43.27	Fusion of spine, lumbosacral region
M43.28	Fusion of spine, sacral and sacrococcygeal region
M46.40-M46.49	Discitis, multiple sites (code range)
M47.10	Other spondylosis with myelopathy, site unspecified
M47.20	Other spondylosis with radiculopathy, site unspecified
M47.819	Spondylosis without myelopathy or radiculopathy, site unspecified
M47.899-M47.9	Spondylosis, unspecified (code range)
M48.00	Spinal stenosis, site unspecified
M50.00-M51.07	Cervical disc disorder with myelopathy, cervical region (code range)
M51.24-M5.19	Other intervertebral disc displacement, thoracic region (code range)
M53.2x7-M53.2x8	Spinal instabilities, lumbosacral sites (code range)
M53.3	Sacrococcygeal disorders, not elsewhere classified
M53.86-M53.88	Other specified dorsopathies, lumbosacral sites (code range)
M54.11-M54.13	Radiculopathy, cervical area (code range)
M54.2	Cervicalgia
M54.30-M54.5	Sciatica (code range)
M6080-M60.9	Other myositis, specified site (code range)
M79.1	Myalgia

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M79.7	Fibromyalgia
M96.1	Postlaminectomy syndrome, not elsewhere classified
R10.0-R10.9	Abdominal and pelvic pain (code range)

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*key article

KEY WORDS:

Bionicare®, Electrical nerve stimulation, Electrotherapy, IFS, Percutaneous neuromodulation therapy, Transcutaneous nerve stimulation.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) and a Local Coverage Determination (LCD) for TENS units. Please refer to the following NCD and LCD websites for Medicare Members:

NCD SITE: <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=273&ncdver=2&bc=AAAAGAAAAAAA&>

LCD SITE: https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33802&ver=18&CntrctrSelected=137*1&Cntrctr=137&s=41&DocType=Active&bc=AggAAAIBA AAA&

There is currently a National Coverage Determination (NCD) for TENS units for Acute Post-Operative Pain. Please refer to the following NCD website for Medicare Members: <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=145&ncdver=2&bc=AAAAGAAAAAAA&>

There is currently a National Coverage Determination (NCD) for TENS units for Chronic Low Back Pain. Please refer to the following NCD website for Medicare Members: <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=354&ncdver=1&bc=AgAAgAAAAAAA%3d%3d&>