INLAND EMPIRE HEALTH PLAN

IEHP UM Subcommittee Approved Authorization Guidelines

Electrical Stimulation modalities (H-wave stimulation, interferential stimulation)

Policy:

IEHP does not cover any of the following electrical stimulation devices: interferential therapy (IFT) or H-WAVE electrical stimulation devices as each is considered experimental and investigational, or has been unproven for the treatment of any condition including, but not limited to providing relief of pain associated with soft tissue injury, musculoskeletal disorders, or to enhance wound or fracture healing.

Types of Devices Used for Treatment:

H-wave Electrical Stimulation Devices

- H-Wave® Muscle Simulator (Electronic Waveform Lab, Inc., Temecula, CA)

Interferential Therapy Stimulation Devices

Brand Name	**Manufacturer**
BioStim®, INF Plus™	BioMedical Life Systems, Inc., Vista, CA
Endomed 433, 582, 982 Interferential Stimulators	Enraf Nonius, Delft, The Netherlands
Galva Electrotherapy System	Wimmer Elektromedizin, Neu-Ulm, Germany
IF 4000	ProMed Specialties, Huntingdon Valley, PA
IF 8000	Biomotion, Madison, AL
NEO GeneSys 2k-2®	Sanexas Intl., GMBH, Blaustein, GM
Omega Inter 4150	Medical Industries PTY., Ltd., Sydney, Australia
OrthoStim3™, SurgiStim3™, VQ™ Vector	VQ OrthoCare℠, Irvine, CA
RS-4i® Sequential Stimulator; RS-2i® Interferential Stimulator	RS Medical, Vancouver, WA
Siemens Stereodynator® 828 & 928	Gbo Medizintechnik AG, Rimbach, Germany
VacuPulls/VasoPulse	Hako-Med, USA, Inc., Honolulu, HI
Vectorsurge 4 Interferential Therapy Unit-VS 460	Metron Medical-Australia PL, Victoria, Australia
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CMS National Coverage Decision A5331:

The Centers for Medicare and Medicaid Services (CMS) has issued a national coverage decision (NCD) in the Medicare Coverage Issues Manual, section 60-9 stating that, effective for dates of service on or after April 1, 2003, electrical stimulation devices used for the treatment of wounds in the home setting will not be covered. Use of these devices in the home setting will be denied as not medically necessary. "Medicare will not cover any form of electromagnetic therapy for the treatment of chronic wounds."

Apollo:

Most health plans and Medicare, including Aetna, do not cover the following electrical stimulation therapies because their safety and effectiveness have not been adequately established in the peer reviewed medical literature. Electrical stimulation devices proposed to treat these conditions include H-wave stimulation, interferential stimulation, microcurrent stimulation, pulsed electrical stimulation, percutaneous neuromodulation therapy, and sympathetic therapy devices.

Peer Reviewed Literature:

Interferential Stimulation:

It has been claimed that IFS is highly effective in reducing (1) pain and use of pain medications, (2) edema and inflammation, (3) healing time, as well as in improving (A) range of motion, (B) activity levels, and (C) quality of life. However, there are very few well designed studies such as randomized, double blind, controlled clinical trials that support such claims. Low (1988) stated that in spite of widespread agreement among physiotherapists that IFS has a marked pain relieving effect, there is a paucity of objective investigations into this analgesic effect. He claimed that both the therapeutic and physiological effects of interferential currents require further investigation. Reitman and Esses (1995) noted that there were no controlled studies proving the effectiveness of IFS. Indergand and Morgan (1995) reported that interferential current applied over the stellate ganglion did not change forearm hemodynamics in asymptomatic individuals. The authors stated that these findings challenged the concept that IFS can block sympathetic vasoconstrictor impulses in peripheral nerves. Poitras and Brosseau (2008) conducted a structured systematic review of management of back pain with therapeutic modalities including transcutaneous electrical nerve stimulation (TENS) and interferential current. The authors found no eligible studies on which to base recommendations for interferential stimulation.

In a randomized placebo controlled study, Van Der Heijden, et al. (1999) evaluated the effectiveness of bipolar interferential electrotherapy (ET) and pulsed ultrasound (US) as adjuvants to exercise therapy for soft tissue shoulder disorders (n = 180). Patients with shoulder pain and/or restricted shoulder mobility, because of soft tissue impairment without underlying specific or generalized condition, were randomized to receive (1) active ET plus active US; (2) active ET plus dummy US; (3) dummy ET plus active US; (4) dummy ET plus dummy US; or (5) no adjuvants. Additionally, they received a maximum of 12 sessions of exercise therapy in 6 weeks. Measurements at baseline, 6 weeks and 3, 6, 9, and 12 months later were blinded for treatment. Outcome measures: recovery, functional status, chief complaint, pain, clinical status, and range of motion. At the 6th-week, 7 patients (20 %) without adjuvants reported very large

improvement (including complete recovery), 17 (23 %) and 16 (22 %) with active and dummy ET, and 19 (26 %) and 14 (19 %) with active and dummy US. These proportions increased to about 40 % at the 3rd-months, but remained virtually stable thereafter. The authors concluded that neither ET nor US proved to be effective as adjuvants to exercise therapy for soft tissue shoulder disorders.

Jarit, et al. (2003) concluded that home IFS may help reduce pain, pain medication taken, and swelling while increasing range of motion in patients undergoing knee surgery. This could result in quicker return to activities of daily living and athletic activities. Drawbacks of this study were as follows: (1) while placebo subjects did consume more medications at all time points, the difference was only at some points, and (2) a functional assessment scale was not used. The findings of this study need to be validated by further investigation. Furthermore, a technology assessment by the California Technology Assessment Forum (CTAF, 2005) concluded that interferential stimulation does not meet CTAF's assessment criteria.

A review on non-pharmacological therapies (including IFS) for acute and chronic low back pain by the American Pain Society and the American College of Physicians (Chou et al, 2007) concluded that therapies with good evidence of moderate efficacy for chronic or sub-acute low back pain are cognitive-behavioral therapy, exercise, spinal manipulation, and inter-disciplinary rehabilitation. For acute low back pain, the only therapy with good evidence of efficacy is superficial heat.

H-Wave Stimulation:

The H-wave stimulator (Electronic Waveform Lab, Inc., Huntington Beach, CA) is an electrostimulation device that has been used to reduce pain and swelling associated with a variety of diseases and conditions. In a single-blinded clinical study, Kumar and Marshall (1997) evaluated the effectiveness of H-wave stimulation for the treatment of chronic (greater than 2 months) pain associated with diabetic (type 2) peripheral neuropathy (n = 31). Patients were randomly assigned to (i) H-wave stimulation, or (ii) sham treatment. The authors reported that H-wave treated patients exhibited greater symptomatic relief than their sham-treated counterparts. Moreover, it has also been shown that H-wave stimulation may be a useful adjunctive modality when combined with pharmacotherapy (e.g., amitriptyline) to augment symptomatic relief in patients with diabetic peripheral neuropathy (Julka, et al., 1998; McDowell, et al., 1999). Additional sham-controlled studies are needed from other investigators, preferably studies that are clearly blinded, specify the handling of withdrawals, and provide long-term, comparative follow-up data to permit conclusions about the effectiveness of this modality for the treatment of diabetic neuropathy.

On the other hand, H-wave stimulators have not been shown to be effective in reducing pain from causes other than chronic diabetic peripheral neuropathy, or in reducing edema or swelling. In particular, H-wave stimulation has not been demonstrated to be effective in treating chronic pain due to ischemia. In the study by Kumar and Marshall, patients with significant peripheral vascular disease were excluded from the trial. Furthermore, in a randomized controlled study (n = 112), McDowell, et al. (1995) reported that H-wave stimulation was not effective in reducing experimental ischemic pain.

Aetna Clinical Policy bulletin Electrical Stimulation for pain Number 0011:

Aetna considers H-WAVE ® type stimulators medically necessary DME for members who have failed to adequately respond to conventional treatments of diabetic peripheral neuropathy.

Note: Conventional therapies of diabetic peripheral neuropathy include analgesics, topical capsaicin cream, tricyclic anti-depressants, selective serotonin re-uptake inhibitors, anti-seizure medications such as carbamazepine (Tegretol), gabapentin (Neurontin), mexiletine (Mexitil), as well as normalization of blood glucose.

Aetna considers H-WAVE ® type stimulators experimental and investigational for all other indications including *any* of the following indications because their effectiveness for these indications has not been established.

1. To reduce pain from causes other than chronic diabetic peripheral neuropathy; *or*
2. To reduce edema; *or*
3. To accelerate healing; *or*
4. To treat chronic pain due to ischemia.

A. Aetna considers intramuscular stimulation experimental and investigational for the management of members with soft-tissue or neuropathic pain and all other indications because its effectiveness has not been established.

B. Aetna considers interferential stimulation (e.g., RS-4i Sequential Stimulator) experimental and investigational for the reduction of pain and edema, and all other indications because its effectiveness for these indications has not been established.

Anthem Blue Cross Electrical Stimulation as a Treatment for Pain and Related Conditions: Surface and Percutaneous Devices DME.00011

Investigational and Not Medically Necessary:

H-wave electrical stimulation devices are considered **investigational and not medically necessary** to reduce pain from all causes including, but not limited to, pain associated with diabetic peripheral neuropathy.

Interferential therapy (IF) devices are considered **investigational and not medically necessary** for all indications, including, but not limited to providing relief of pain associated with soft tissue injury, musculoskeletal disorders, or to enhance wound or fracture healing.

Background:

Interferential Stimulation:

Interferential stimulation (IFS) is a type of electrical stimulation that uses paired electrodes of two independent circuits carrying high-frequency (4,000 Hz) and medium-frequency (150 Hz) alternating currents. The superficial electrodes are aligned on the skin. It is believed that IFS permeates the tissues more effectively, with less unwanted stimulation of cutaneous nerves, and is more comfortable than transcutaneous electrical stimulation (TENS). Interferential currents

reportedly can stimulate sensory, motor, and pain fibers. This deep tissue penetration can be adjusted to stimulate parasympathetic nerve fibers for increased blood flow. According to proponents, interferential stimulation differs from TENS because it allows a deeper penetration of the tissue with more comfort (compliance) and increased circulation.

H-Wave Stimulation:

H-wave stimulation delivers electrical stimulation in the form of milliamperage. H-wave stimulation is intended to emulate the H waveform found in nerve signals (Hoffman Reflex); and therefore, enables greater and deeper penetration of a low frequency current, while using significantly less power than other machines. This allegedly makes H-Wave stimulation much safer, less painful, and more effective than other forms of electrotherapy to date. The H-wave signal is a bipolar exponential decaying waveform that supposedly overcomes the disadvantages of other electrotherapy machines. It allows the therapist to apply two treatments at the same time: (1) low-frequency muscle stimulation, and (2) high-frequency deep analgesic pain control (a "TENS" effect).

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Revised:

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