



# CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

**Subject Pulsed Electromagnetic Therapy**

**Effective Date ..... 11/15/2010**  
**Next Review Date ..... 11/15/2011**  
**Coverage Policy Number ..... 0236**

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Electrical Stimulation for Wound Healing  
 Negative-Pressure Wound  
 Therapy/Vacuum-Assisted Closure  
 (VAC) for NonHealing Wounds  
 Tissue-Engineered Skin Substitutes and  
 Platelet-Derived Growth Factors

### INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2010 CIGNA

## Coverage Policy

**CIGNA does not cover pulsed electromagnetic therapy (e.g., Diapulse<sup>®</sup>, SofPulse<sup>®</sup>, Provant<sup>®</sup> Wound Closure System) for any indication, including wound care management, because it is considered experimental, investigational or unproven.**

## General Background

Electromagnetic therapy, often termed pulsed electromagnetic field (PEMF), has been proposed as an alternative treatment for chronic wounds that do not heal with standard therapy. Although similar to electrical stimulation, electromagnetic therapy uses an electromagnet to generate electrical current and uses nonthermal pulsed electromagnetic energy to deliver the current. This modality of treatment has been shown to induce various responses (e.g., increased blood flow, collagen formation, granulocyte infiltration) in both in vitro and animal models, to induce wound healing (Blue Cross and Blue Shield Association Technology Evaluation Center [BCBSA TEC], 2005).

In contrast to electrical stimulation, electromagnetic therapy does not involve the use of current, leads, or electrodes. Pulsed electromagnetic devices that are used for wound therapy utilize generators designed to create radiofrequency signals that are typically delivered through coils which do not directly contact the skin. In relation to chronic wound treatment, electromagnetic therapy primarily refers to pulsed electromagnetic fields in the radiofrequency band without thermal effects. It has been suggested that pulsed electromagnetic therapy

stimulates blood flow by a rapid peristaltic mechanism on the vessel walls, rather than a heating action or by secondary vasodilatation, and promotes cell proliferation for wound healing.

Another type of electromagnetic therapy, shortwave diathermy (continuous or pulsed), is often used for the treatment of pain. It uses radiofrequency electromagnetic fields for therapeutic heating of tissue.

Pulsed electromagnetic therapy (PEMF) has also been recommended for treatment of painful injuries or inflammation. Evidence in the scientific literature suggests that PEMF results in vasodilatation, modification of the inflammatory process, reduction of edema, and enhanced tissue repair. Several devices are available and utilize varying frequencies, field strength, and pulse widths although there is little published data to support selection of any of these devices (Fernandez, et al. (2007).

### **U.S. Food and Drug Administration (FDA)**

A number of devices used for electromagnetic therapy have been approved by the FDA through the 510(k) approval process. When used to treat wounds the FDA considers these devices as Class III devices which require a premarket approval. Some of these devices have been cleared by the FDA more specifically as short-wave diathermy devices or radiofrequency stimulation devices (e.g., Provant Wound Closure System [Regenesis<sup>®</sup> Biomedical, Scottsdale, AZ]; Diapulse<sup>®</sup> [Diapulse Corporation of America, Great Neck, NY]; SofPulse<sup>®</sup> [Electropharmacology, Inc., Alachoa, FL]). Several of the devices are intended for the treatment of postoperative pain and edema in superficial tissue and not specifically for wound treatment. Approval for the use of these devices specifically for the treatment of chronic wounds was not found on the FDA site.

### **Literature Review**

**Wound Care Management:** Studies in the published medical literature comparing electromagnetic therapy devices with established wound care management are lacking. The clinical studies evaluating the devices and clinical outcomes have been few, are limited in sample size with poorly-defined patient selection criteria, and have limited reporting of methodologic details (Ravaghi, et al., 2006; Olyae Manesh, et al., 2006; Ritz, et al., 2003). There is little consensus among authors regarding duration of treatment or technique of application. Two published Cochrane reviews assessed the effects of electromagnetic therapy on wounds, one evaluated venous leg ulcers (Ravaghi, et al., 2006) and a second evaluated the healing of pressure ulcers (Olyae Manesh, et al., 2006). The results of both reports provided no evidence of benefit to electromagnetic therapy when used for wound healing. In addition, a systematic review (Reddy, et al., 2008) found minimal data to support therapies such as electromagnetic therapy for the treatment of pressure ulcers.

In one study, the Provant Wound Closure System was specifically evaluated. Ritz et al. (2003) published the results of a randomized trial involving 49 patients with pressure ulcers who received standard wound therapy combined with the Provant Wound Closure System. The results indicate that when compared to a placebo (modified Provant device), Stage II wounds treated with Provant healed faster (26 days versus 66 days, respectively). The authors also reported that Provant-treated wounds showed an average 87% reduction in surface area compared to a 56% reduction for placebo; however no time period was specified. Furthermore, the authors did not compare outcomes with other effective, established wound closure devices or treatments making comparisons difficult.

In an earlier publication, George et al. (2002) reported on a series of in-vitro studies that evaluated cellular mechanisms involved in cell proliferation induction (CPI). CPI theoretically employs sensation-free radiofrequency (RF) stimuli to stimulate dormant cells in damaged wound tissue, and is a technique associated with the Provant Wound Closure System. The authors confirmed that CPI-induced proliferation of fibroblasts and epithelial cells varies as a function of both the treatment dose and the duration of treatment; the author's further hypothesized CPI treatment may accelerate wound closure.

In August 2005, the BCBSA TEC (2005) reviewed the available evidence for electrical stimulation and electromagnetic therapy for chronic wounds. A total of five studies involving 155 patients were reviewed. The panel concluded that the available evidence did not convincingly demonstrate electrical stimulation or electromagnetic therapy led to significant health outcome benefits on the most important clinical outcome, (i.e., number of patients who heal completely). BCBSA TEC concluded that the evidence was not sufficient to permit conclusions regarding the efficacy of electromagnetic therapy or electrical stimulation as an adjunctive treatment for wound healing.

**Miscellaneous Indications:** Evidence in the published peer-reviewed scientific literature evaluating PEMF for conditions other than wound management consists mainly of case series with few randomized controlled trials. PEMF theoretically offers some potential benefit and has been utilized for the treatment of numerous conditions, such as subacromial impingement syndrome, lateral epicondylitis, tinnitus, soft tissue injuries, fibromyalgia, diabetic peripheral neuropathy, and for various other conditions related to pain (Ogilvie-Harris, et al., 1995; Ghossaini, et al., 2004; Uzunca, et al., 2007; Fernandez, et al., 2007; Aktas, et al., 2007; Thomas, et al., 2007; Heden and Pilla, 2008, Ay and Evcik 2009; Sutbeyaz, et al., 2010). When employed for the treatment of pain, study results are mixed, some authors report no difference in pain among study groups (Aktas, et al., 2007; Fernandez, et al., 2007, Ay and Evcik, 2009) while others report improvement in various pain parameters after PEMF therapy (Uzunca, et al., 2007; Thomas, et al., 2007; Heden and Pilla, 2008). In some studies, despite improvement in pain, other treatment modalities were used making study interpretations and comparisons difficult (Ay and Evcik, 2009).

In a recent randomized controlled trial Foley et al. (2008) evaluated the efficacy of PEMF stimulation as an adjunct to cervical arthrodesis in patients with potential risk factors for nonunion (i.e., active smokers or undergoing multilevel fusion). The study group involved 323 individuals randomized to two groups: those receiving PEMF after surgery (n=163) and those not receiving PEMF (n=160). Follow-up was carried out at one, two, three, six and 12 months post-operatively. At six months the PEMF group had a significantly higher fusion rate than the control group (83.6% versus 68.6%); however at 12 months the fusion rates were comparable: the PEMF group had a fusion rate of 92.8% while the control group had a fusion rate of 86.7%. Although PEMF improved bone healing, there was no significant advantage in terms of fusion rate or clinical outcomes.

The effects of PEMF on diabetic neuropathy have also been investigated. Wrobel, et al. (2009) published the results of a randomized placebo-controlled double blind study to determine whether low frequency magnetic field can influence pain intensity, quality of life and sleep, and glycemic control in patients with painful diabetic polyneuropathy (n=61). The authors noted that both treatment and control groups demonstrated a significant reduction in pain intensity after the first week of treatment that persisted until the end of the follow-up period (five weeks), with no significant differences between groups. Similar improvements were noted in quality of life values, with no significant differences between groups. In the authors opinion there was no advantage to low frequency pulsed electromagnetic field stimulation compared to sham therapy for the outcomes measured. Weintraub et al. (2009) reported the results of a randomized double-blind controlled trial evaluating the effects of PEMF therapy in reducing diabetic neuropathic pain, influencing sleep, and for nerve regeneration. The study group involved 225 individuals randomly assigned to receive either PEMF or sham treatment. Outcomes were measured using a visual analog score (VAS), Neuropathy Pain Score (NPS), and the Patients Global Impression of Change (PGIC). There was a trend to a reduction in the PGIC score in favor of the PEMF group, however there were no significant differences between groups in neuropathic pain intensity or VAS. PEMF was not effective in reducing diabetic neuropathic pain. Pieber et al. (2010) reviewed the evidence evaluating different types of electrotherapy for the treatment of diabetic peripheral neuropathy and noted conflicting results for pulsed and static electromagnetic therapy; some studies reported the treatment was not effective and some studies reported a short-term analgesic effect (Pieber, et al., 2010). The authors noted differences in study designs, the use of various stimulating patterns, and inconsistent outcomes made comparisons across studies difficult.

Vavken, et al (2009) published a meta-analysis evaluating the effectiveness of pulsed electromagnetic fields for the management of osteoarthritis of the knee. In all, nine randomized controlled trials were reviewed reporting on a total of 483 patients. Although there was a significant effect of PEMF six weeks after treatment in activities of daily living, there was no significant difference in pain between treatment group and controls. The authors acknowledged PEMF may be useful and effective in addition to conservative management of osteoarthritis of the knee, although future studies are needed to confirm their findings.

## **Summary**

There is insufficient evidence in the published, scientific literature to support the effectiveness of pulsed electromagnetic field therapy (e.g., Diapulse, SofPulse, Provant Wound Closure System) for wound care management. Studies comparing these devices with established wound care management modalities are lacking. The clinical studies have been few, limited in size and design, with poorly-defined patient selection criteria and limited reporting of methodologic details. Additionally, data are limited evaluating these devices for other indications such as pain or soft tissue injuries and clinical efficacy has not been firmly established in the peer-reviewed published scientific literature when used for these indications.

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## Coding/Billing Information

**Note:** This list of codes may not be all-inclusive.

### Experimental/Investigational/Unproven/Not Covered:

<b>HCPCS Codes</b>	<b>Description</b>
E0761	Non-thermal pulsed high frequency radiowaves, high peak power electromagnetic energy treatment device
E0769	Electrical stimulation or electromagnetic wound treatment device, not otherwise classified
G0295	Electromagnetic stimulation, to one or more areas, for wound care other than described in G0329 or other use
G0329	Electromagnetic therapy, to one or more areas for chronic stage III and stage IV pressure ulcers, arterial ulcers, diabetic ulcers and venous stasis ulcers not demonstrating measurable signs of healing after 30 days of conventional care as part of a therapy plan of care.

<b>ICD-9-CM Diagnosis Codes</b>	<b>Description</b>
337.1	Peripheral autonomic neuropathy in disorders classified elsewhere
357.2	Polyneuropathy in diabetes
388.30-388.32	Tinnitus
707-707.9	Chronic ulcer of skin
726.32	Lateral epicondylitis
729.1	Myalgia and myositis, unspecified
729.9	Disorders of soft tissue, unspecified
782.3	Edema
	All other codes

\*Current Procedural Terminology (CPT®) © 2010 American Medical Association: Chicago, IL.

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## Policy History

<b>Pre-Merger Organizations</b>	<b>Last Review Date</b>	<b>Policy Number</b>	<b>Title</b>
CIGNA HealthCare	11/15/2007	0236	Pulsed Electromagnetic Stimulation Therapy

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Connecticut General Life Insurance Company has acquired the business of Great-West Healthcare from Great-West Life & Annuity Insurance Company (GWLA). Certain products continue to be provided by GWLA (Life, Accident and Disability, and Excess Loss). GWLA is not licensed to do business in New York. In New York, these products are sold by GWLA's subsidiary, First Great-West Life & Annuity Insurance Company, White Plains, N.Y.