



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 Electrical Stimulation for Wound Healing

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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 ©2009 CIGNA

Coverage Policy

CIGNA covers electrical stimulation (ES) using low-intensity direct current (LIDC), high-voltage pulsed current (HVPC) and/or alternating current (AC) as medically necessary for the treatment of chronic wounds when ALL of the following criteria are met:

- Presence of **ANY** of the following chronic wound types:
 - Stage III or Stage IV pressure ulcers
 - arterial ulcers
 - neuropathic (diabetic) ulcers
 - venous stasis ulcers

- Failure to demonstrate measurable signs of improved healing with a 30-day trial of conventional wound management, including optimization of nutritional status, moist dressings, and debridement.
- ES therapy is performed under the direct supervision of a medical professional with expertise in wound evaluation and management.

CIGNA does not cover the unsupervised use of ES therapy for wound healing performed by the individual in the home setting because it is considered experimental, investigational or unproven.

General Background

Chronic wounds, also known as ulcers, are wounds that have a biological or physiologic reason for not healing. Chronic wounds have not completed the process of healing in the expected period, or have proceeded through the healing phase without establishing the expected functional result. These wounds generally do not close without intervention and are sometimes unresponsive to healing interventions. Diabetic foot ulcers/sores, pressure ulcers or bed sores, venous leg ulcers, and sternal wound infections are all considered chronic wounds because their etiologies delay and prevent healing and they persist without proper medical care (ECRI, 2008).

While there are numerous treatments that have been proposed to treat chronic wounds, some have not been well-studied and therefore their safety and effectiveness are as yet unproven. Proposed approaches include: ultrasound, laser, electromagnetic therapy (EM), electrical stimulation (ES), hyperbaric oxygen, gene therapy, surgical debridement, surgical revascularization of the affected area, myocutaneous skin flaps or grafting, wet-to-dry dressings, negative pressure wound therapy, vacuum-assisted closure, and the use of certain bioengineered skin substitutes. When clinically appropriate, all of these interventions are used in combination with aggressive medical management of the underlying wound etiology.

Chronic Wound Types

Pressure Ulcers: A pressure ulcer is a result of pathologic changes in blood supply to the dermal and underlying tissues, usually because of compression of the tissue over a bony prominence. Chronic ulcers of the skin include arterial ulcers, venous stasis ulcers, diabetic ulcers, and pressure ulcers (Thomas, 2008).

Staging of Pressure Ulcers

When evaluating pressure ulcers, a staging system is typically used that measures tissue destruction by classifying wounds according to the tissue layers involved. In 2007, the National Pressure Ulcer Advisory Panel (NPUAP) redefined the definition of a pressure ulcer and the stages of pressure ulcers, including the original four stages and adding two stages on deep tissue injury and unstageable pressure ulcers. The stages are defined by the NPUAP as follows:

- Suspected Deep Tissue Injury: Purple or maroon localized area of discolored intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or shear. The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer or cooler as compared to adjacent tissue.

Further description: Deep tissue injury may be difficult to detect in individuals with dark skin tones. Evolution may include a thin blister over a dark wound bed. The wound may further evolve and become covered by thin eschar. Evolution may be rapid exposing additional layers of tissue even with optimal treatment.

- Stage I: Intact skin with non-blanchable redness of a localized area usually over a bony prominence. Darkly pigmented skin may not have visible blanching; its color may differ from the surrounding area.

Further description: The area may be painful, firm, soft, warmer or cooler as compared to adjacent tissue. Stage I may be difficult to detect in individuals with dark skin tones. May indicate "at risk" persons (a heralding sign of risk).

- Stage II: Partial thickness loss of dermis presenting as a shallow open ulcer with a red pink wound bed, without slough. May also present as an intact or open/ruptured serum-filled blister.

Further description: Presents as a shiny or dry shallow ulcer without slough or bruising. This stage should not be used to describe skin tears, tape burns, perineal dermatitis, maceration or excoriation. Bruising indicates suspected deep tissue injury.

- Stage III: Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscle are not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunneling.

Further description: The depth of a stage III pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput and malleolus do not have subcutaneous tissue and stage III ulcers can be shallow. In contrast, areas of significant adiposity can develop extremely deep stage III pressure ulcers. Bone/tendon is not visible or directly palpable.

- Stage IV: Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present on some parts of the wound bed. Often include undermining and tunneling.

Further description: The depth of a stage IV pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput and malleolus do not have subcutaneous tissue and these ulcers can be shallow. Stage IV ulcers can extend into muscle and/or supporting structures (e.g., fascia, tendon or joint capsule) making osteomyelitis possible. Exposed bone/tendon is visible or directly palpable.

- Unstageable: Full thickness tissue loss in which the base of the ulcer is covered by slough (yellow, tan, gray, green or brown) and/or eschar (tan, brown or black) in the wound bed.

Further description: Until enough slough and/or eschar is removed to expose the base of the wound, the true depth, and therefore stage, cannot be determined. Stable (dry, adherent, intact without erythema or fluctuance) eschar on the heels serves as "the body's natural (biological) cover" and should not be removed.

Arterial Ulcers: Arterial ulcers of the lower limb account for approximately 10–20% of leg ulcers. They are caused by an insufficient arterial blood supply resulting in tissue ischemia and necrosis. Reestablishment of an adequate vascular supply is a key factor to support proper healing. Medical management includes control of diabetes, control of hypertension, smoking cessation, and moderate exercise (Bello, 2000).

Venous Stasis Ulcers: Venous stasis occurs due to the incompetence of either the superficial or deep venous systems. Chronic venous ulcers are usually due to the incompetence of the deep venous system and are commonly painless. The consensus is unclear as to the exact pathophysiologic process that leads to ulceration and impaired healing with venous ulcers. Regardless of the pathophysiologic mechanisms, the characteristic clinical picture is that of an ulcer that fails to re-epithelialize despite the presence of adequate granulation tissue. The wound is usually shallow with irregular margins and pigmented surrounding skin (Barbul, 2005).

Compression therapy is the primary therapy for the management of venous ulcers. The goal of compression therapy is to counteract venous hypertension by facilitating venous return toward the heart. Several different compression devices are available, including compression pumps, elastic and nonelastic bandages, orthotic devices, and compression stockings (Phillips, et al., 2008).

Neuropathic Diabetic Ulcers: The major contributors to the formation of diabetic ulcers include neuropathy, foot deformity, and ischemia. It is estimated that 60–70% of diabetic ulcers are due to neuropathy, 15–20% are due to ischemia, and another 15–20% are due to a combination of both. The neuropathy is both sensory and motor and is secondary to persistently elevated glucose levels. Maintaining optimal blood sugar levels is important. The management of diabetic wounds involves local and systemic measures. Treatment options include relief of pressure at the wound site, surgical debridement, control of infection, and arterial reconstruction. It is recommended that treatment should address the possible presence of osteomyelitis, and should employ antibiotics that achieve adequate levels both in the bone and soft tissue. Other therapeutic options include

recombinant human growth factors, bioengineered skin substitutes, dressings comprised of extracellular matrix protein, and a variety of synthetic dressings (Barbul, 2005).

Electrical Stimulation (ES)

Electrical current has been recommended as an adjuvant therapy in the treatment of chronic wounds. ES involves the placement of electrodes in direct contact, or in close proximity, to a skin wound, thereby creating an electrical current that passes through the wound. The use of ES as an adjunctive treatment for wound healing has been proposed for many years, since the recognition that the skin possesses an electrical field, and the presence of a wound disrupts this electrical field. There are several modalities of ES used in the treatment of chronic wounds. Some apply ES (e.g., low-intensity direct current (LIDC), low-intensity pulsed current (LIPDC), or high-voltage pulsed current (HVPC) into the wound or its vicinity (Ho, 2008; Fernandez, 2004).

- LIDC involves application of a direct current (i.e., the flow of electrons in one direction only) of low intensity, typically between 100 μ A (microamperes) and 1 mA (milliampere).
- LIPDC involves application of a pulsed direct current of about 10 mA, with a pulse repetition on the order of 100 pulses per second.
- HVPC consists of the application of a pulsed direct current of high voltage. The pulses are usually twin pulses of short duration, from 100–500 volt (V) electrical potential.

There are several theories as to how ES may stimulate wound healing. When wounding occurs, there is a weak but measurable current between the skin and inner tissues called the current of injury. It is thought that the current continues until the skin defect is repaired and that the healing process is interrupted if the current ceases (Fernandez, 2004). ES may mimic the current of injury restarting or accelerating the wound healing process (e.g., cells may be stimulated to move along the path of the electrical current, and this migration of cells may be important in the inflammatory and proliferative stage of the healing process). Electrical currents are believed to stimulate several cell activities (e.g., deoxyribonucleic acid [DNA] synthesis, cell proliferation, synthesis of extracellular matrix, collagen, expression of growth factors and receptors) (Zhao, 1999). Local electrical currents may improve arterial blood flow, reduce tissue edema, microvascular permeability and have antibacterial effects. The extent to which ES stimulates wound healing rates is unclear (Fernandez, 2004). Zhao et al. (2006) report that by using multiple models, they have shown that electric currents can act as directional cues in cell movement and wound healing. Electric fields couple to directed cell migration through PI(3)Kgamma and PTEN signaling. Their experiments identify the first genes that modulate cell movements and wound healing in response to electric currents.

Studies have not adequately evaluated unsupervised home use of the device by a patient (CMS, 2002). Risks are uncommon but may occur with unsupervised treatments, including rashes at the site of electrode placement or, in rare cases, burns on the skin. Evaluation of the wound is an integral part of wound therapy.

U.S. Food and Drug Administration (FDA)

In a Centers for Medicare & Medicaid Services (CMS) decision memorandum (2003), the FDA granted premarket application (PMA) approvals for electrical stimulators as Class III devices for the indications of bone stimulation and deep brain stimulation. FDA has also cleared electrical stimulators as Class II devices when indicated for muscle stimulation. However, the FDA has not cleared or approved the use of ES for the treatment of wounds. The FDA concluded that the use of these devices for the treatment of wounds is significantly different than the use of these devices for the indications currently covered under a 510(k) clearance. They are considered Class III devices and, as such, require approval via the PMA process. Manufacturers cannot market electrical stimulators for wound healing. However, lack of approval does not preclude physicians and other healthcare providers from providing this therapy as an off-label use. ES used as adjunctive treatment for chronic wound healing should be conducted under the direct supervision of a medical professional with expertise in wound evaluation and management.

Literature Review

Many aspects of treatment with ES have been studied. Several randomized controlled trials (RCTs) have evaluated ES with varying protocols using different currents and voltages for the healing of pressure ulcers, venous stasis ulcers, arterial ulcers, surgical wounds, and diabetic foot wounds. Some trials provided a placebo control for the ES, while others compared results obtained using standard wound care alone. Many of the studies reported that as an adjunctive therapy, ES improved the rate or extent of wound healing compared to

standard wound care alone (Jünger, et al., 2008; Houghton, et al., 2003; Hayes, 2003; Peters, et al.; 2001; Baker, et al., 1997).

Meta-Analysis: Akai et al. (2002) conducted a meta-analysis to examine ES effects using direct current (DC), alternating current (AC), pulsing electromagnetic and other types of ES in the musculoskeletal repair process. A total of 29 RCTs that dealt with skin wounds, dermal ulcers, soft tissue injury, and other conditions were identified. The authors report that the majority of the studies exhibited statistically significant positive findings. The studies in the review had some methodological limitations, including ill-defined patient selection criteria, lack of long-term outcomes, and failure of the selected pooled trials to provide acceptable proof that ES has specific effects on soft tissue healing. However, the authors reported that the statistically significant positive (i.e., a pooled difference [n=613] of 0.42, 95% confidence interval [CI=0.31–0.53]) findings reported in the trials from which the extracted data were able to be combined cannot be ignored.

Agency for Health Care Research and Quality (AHRQ): The panel examined the roles of several adjunctive therapies in supporting pressure ulcer healing. These therapies include: electrotherapy; hyperbaric oxygen, infrared, ultraviolet, and low-energy laser irradiation, ultrasound, miscellaneous topical agents (including cytokine growth factors), and systemic drugs other than antibiotics. Although many of these therapies hold promise for the future, ES is the only adjunctive therapy with sufficient supporting evidence to warrant recommendation at this time. The panel recommends that a course of ES be considered for Stage III and IV pressure ulcers that do not respond to conventional therapy. The panel recommends reassessing pressure ulcers at least weekly. If the condition of the patient or of the wound deteriorates, it is recommended to reevaluate the treatment plan as soon as any evidence of deterioration is noted. It is noted that a clean pressure ulcer should show evidence of some healing within 2–4 weeks. If no progress can be demonstrated, it is recommended to reevaluate the adequacy of the overall treatment plan as well as adherence to this plan, making modifications as necessary (Bergstrom, et al., 1994).

Professional Societies/Organizations

Wound Ostomy and Continence Nursing Society (WOCN): WOCN considers ES as an adjunctive therapy to enhance the healing of recalcitrant Stage III and IV wounds (WOCN, 2003).

Summary

There is sufficient peer-reviewed scientific evidence to support the use of electrical stimulation (ES) as an adjunctive therapy in the treatment of chronic wounds when a trial of conventional wound care methods has failed to show measurable signs of healing. Studies have shown that ES plays a contributory role in the management of difficult chronic wounds (e.g., Stage III or Stage IV pressure ulcers, arterial diabetic ulcers and venous stasis ulcers). Risks are uncommon but may occur with unsupervised treatments, including rashes at the site of electrode placement or, in rare cases, burns on the skin. Evaluation of the wound is an integral part of wound therapy.

Coding/Billing Information

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

Covered when medically necessary:

HCPSC Codes	Description
G0281	Electrical stimulation, (unattended), 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

ICD-9-CM Diagnosis Codes	Description
250.80-	Diabetes with other specified manifestations

250.83	
447.8	Other specified disorders of arteries and arterioles
454.0	Varicose veins of lower extremities with ulcer
454.2	Varicose veins of lower extremities with ulcer and inflammation
459.11	Postphlebitic syndrome with ulcer
459.13	Postphlebitic syndrome with ulcer and inflammation
707.00-707.9	Chronic Ulcer of the skin

Experimental/Investigational/Unproven/Not Covered:

HCPCS Codes	Description
G0282	Electrical stimulation, (unattended), to one or more areas, for wound care other than described in G0281

***Current Procedural Terminology (CPT®) ©2008 American Medical Association: Chicago, IL.**

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Policy History

<u>Pre-Merger Organizations</u>	<u>Last Review Date</u>	<u>Policy Number</u>	<u>Title</u>
CIGNA HealthCare	5/15/2008	0351	Electrical Stimulation for Wound Healing

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