



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 Bone Growth Stimulators:
Electrical (Invasive,
Noninvasive), Ultrasound**

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Lumbar Fusion for Spinal Instability and Degenerative Disc Conditions

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

Coverage for ultrasound and noninvasive electrical bone growth stimulators is subject to the terms, conditions and limitations of the applicable benefit plan's Durable Medical Equipment (DME) benefit and schedule of copayments. Invasive bone growth stimulators are considered internal medical devices and, therefore, are covered under the core medical benefits of many plans. Please refer to the applicable benefit plan document to determine benefit availability and the terms, conditions and limitations of coverage.

If coverage is available for bone growth stimulators, the following conditions of coverage apply.

CIGNA covers an ultrasound bone growth stimulator in skeletally mature individuals as medically necessary for ANY of the following conditions:

- When used as an adjunct to closed reduction and immobilization for ANY of the following acute fracture indications:
 - closed or grade I open, tibial diaphyseal fractures
 - closed fractures of the distal radius (Colles' fracture)
 - closed fractures when there is suspected high risk for delayed fracture or nonunion as a result of either of the following:

- due to location and poor blood supply (e.g., scaphoid, 5th metatarsal)
 - the presence of comorbidities (e.g., smoking, diabetes, renal disease, or other metabolic disease where bone healing is likely to be compromised)
- For nonunion of fractures when ALL of the following criteria are met:
 - The treatment is for nonunion of bones other than the skull or vertebrae (e.g., radius, ulna, humerus, clavicle, tibia, femur, fibula, carpal, metacarpal, tarsal, or metatarsal).
 - The fracture gap is ≤ 1 cm
 - The nonunion is not related/due to malignancy.
 - It is \geq three months from the date of injury or initial treatment.
 - The fracture nonunion is documented by at least two sets of appropriate imaging studies separated by a minimum of 90 days confirming that clinically significant fracture healing has not occurred.
- For treatment of a stress fracture that has failed a minimum of 90 days of conventional, nonsurgical management and demonstrates a fracture line that has not healed on imaging studies.

CIGNA covers an electrical bone growth stimulator (i.e., noninvasive or invasive) in skeletally mature individuals as medically necessary for ANY of the following conditions:

- The treatment is for a fracture nonunion, and ALL of the following criteria are met:
 - The nonunion is located in a long bone (i.e., clavicle, humerus, radius, ulna, femur, tibia, fibula, metacarpal or metatarsal bone) or the carpal and tarsal bones.
 - The fracture gap is ≤ 1 cm.
 - The fracture nonunion is documented by at least two sets of appropriate imaging studies separated by a minimum of 90 days confirming that clinically significant fracture healing has not occurred.
- When used in conjunction with surgical intervention for the treatment of an established fracture nonunion.
- For failed fusion of a joint other than the spine when a minimum of three months has elapsed since the time of initial surgery.
- For treatment of a stress fracture that has failed a minimum of 90 days of conventional, non-surgical management and demonstrates a fracture line that has not healed on imaging studies.
- As an adjunct to spinal fusion surgery when ANY of the following criteria are met:
 - History of prior spinal fusion failure
 - Multi-level fusion to be performed
 - Presence of any risk factor for nonhealing such as: smoking, diabetes, renal disease, or other metabolic disease where bone healing is likely to be compromised

CIGNA does not cover the use of a bone growth stimulator, for ANY of the following indications because it is considered experimental, investigational or unproven (this list may not be all-inclusive):

- fresh fractures (other than for the above listed indications)
- toe fractures
- sesamoid fractures
- avulsion fractures
- osteochondral lesions
- displaced fractures with malalignment
- synovial pseudoarthrosis
- the bone gap is either > 1 cm or $>$ one-half the diameter of the bone

General Background

Bones are divided into four major categories. Long bones are found in the extremities and are comprised of a shaft (i.e., diaphysis) and two ends (i.e., epiphyses). Long bones, which form levers, support weight and provide for motion, and include the clavicle, humerus, radius, ulna, femur, tibia, fibula, metatarsals and metacarpals. Short bones, which include the tarsal bones in the foot and carpal bones in the hand, are cube-shaped and are designed for strength. Flat bones provide protection and areas for muscle attachment and include the cranial bones, sternum, ribs, and the scapulae. Irregular bones include the vertebrae, sacrum, coccyx and some facial bones. Sesamoid bones are a type of short bone embedded within a joint capsule or tendon.

Fractured bones heal in several distinct stages. Bone union is evident when sufficient strength and stiffness has been regained, allowing the bone to function as a weight-bearing structure without external support. Delayed union occurs when the healing process is impaired and has not progressed at an average rate for the site and the type of fracture. Delayed union may be evidenced by slow radiographic progress and continued pain and mobility at the fracture site. A nonunion occurs when bone healing has stopped prematurely and will not likely continue without medical intervention.

Several methods are available to evaluate healing and nonunion of a fracture and include radiographs, fluoroscopy, bone scintigraphy and bone scanning. Occasionally, computed tomography (CT) scans, x-ray tomograms and magnetic resonance imaging (MRI) may be used to establish nonunion. Nonunion of long bone fractures is considered by the Centers for Medicare and Medicaid Services (CMS) to exist only when a minimum of two sets of radiographs, obtained prior to starting treatment, are separated by a minimum of 90 days, showing no evidence of fracture healing between the two sets of radiographs (CMS, 2000). Fracture nonunion of bones such as the carpal and tarsal bones (e.g., talus, scaphoid, and calcaneus) should be clearly evident through the entire body of the bone.

Multiple factors play a role in bone healing. At the fracture site, the extent of the bone and soft tissue damage, adequacy of the blood supply, the gap between bone ends and infection may all have an impact on healing. The individual's general health and nutritional status play a significant role in bone healing. Diminished blood flow to the fracture site will often suppress the healing response. Factors that can cause diminished blood flow such as heavy smoking, obesity and malnutrition, diabetes, alcoholism, peripheral vascular disease, increasing age, and use of some medications such as steroids can all impact the rate and quality of bone healing. Other characteristics such as high grade trauma, high grade and open fractures, comminution of the fracture, vertical or oblique fracture pattern, and fracture displacement may also contribute to poor healing of bone (Agency for Healthcare Research and Quality [AHRQ], 2005).

Nonunion is likely to occur when there is limited blood supply to the specific bone or if there is severe trauma, difficulty in controlling mechanical strain, and a propensity for more severe fractures. According to the American Academy of Orthopedic Surgeons (AAOS), toe bones have inherent stability and blood supply. They typically heal with little or no intervention. Bones such as the upper thigh (i.e., femur head and neck); and small wrist bones such as the scaphoid, have a limited blood supply, which can be destroyed if the bones are broken. Bones such as the tibia have a moderate blood supply; however, severe trauma and injury can destroy the internal blood supply or the external supply from overlying skin and muscle (AAOS, 2005). Fracture of the fifth metatarsal (i.e., Jones fracture) frequently results in delayed healing and nonunion despite surgical treatment, generally due to poor blood supply of the proximal metaphyseal diaphyseal region (Nunley, 2001).

Currently, a variety of invasive and noninvasive interventions are used to treat nonunions, including immobilization/casting, open or closed reduction, pins, screw fixation, intramedullary rods and bone grafting. Immobilization is considered the primary treatment for any nonunion. Bone growth stimulators (noninvasive or invasive), may be used instead of or in addition to other interventions to promote bone healing. Implantable devices may be used as an adjunct to planned surgical treatment (e.g., bone grafts, internal/external fixation) of an established nonunion. Ultrasound bone growth stimulating devices are recommended for healing of fresh fractures and nonunion.

There is a paucity of evidence in the peer-reviewed scientific literature and textbook sources to support the clinical utility of bone growth stimulators as a treatment of stress fractures. However, although the evidence is limited, some authors have reported encouraging results and support the use of bone stimulation devices for treatment of stress fracture nonunion (DiGiovanni, et al., 2003; Beck et al., 2007). The results of a questionnaire

sent out to 453 active members of the Orthopedic Trauma Association (OTA) confirms fracture surgeons are using bone growth stimulators to promote healing for the treatment of delayed union, nonunion, acute fracture care and stress fractures (Zura, et al., 2003). With an overall response rate of 43% the majority of the respondents reported using bone growth stimulators for the treatment of delayed union and nonunion (73% electrical and 58% ultrasound). A total of 16% reported they occasionally used bone stimulators for acute fracture care and 19% used stimulators for stress fractures. However, the authors acknowledged that a 43% response rate of this single specialty organization does not signify a consensus of opinion.

Bone growth stimulators are indicated for use only in individuals who are skeletally mature. A person is said to be skeletally mature when all bone growth is complete; the cartilage cells of the growth plate cease to proliferate, the growth plate becomes thinner, is replaced by bone and disappears, and the epiphysis is "closed" or fused with the shaft.

Ultrasound Bone Growth Stimulators

Ultrasound bone growth stimulation is a noninvasive intervention, designed to transmit low-density, pulsed, high-frequency acoustic pressure waves to accelerate healing of fresh fractures and to promote healing of delayed unions and nonunions that are refractory to standard treatment. Ultrasound devices have been proven to stimulate fresh fracture healing and healing of nonunions in humans. Low-intensity ultrasound also has been suggested to enhance healing of fractures that occur in patients with diseases such as diabetes, vascular insufficiency, and osteoporosis, and those taking medications such as steroids, non-steroidal anti-inflammatory drug (NSAID), or calcium channel blockers (Wood, 2003). The exact mechanism for fracture healing is unclear; however, it is thought that ultrasound causes biochemical changes at the cellular level to accelerate bone formation. Some authors hypothesize that ultrasound increases blood flow to the capillaries, enhancing cellular interaction (Rubin, et al., 2001). The device is intended to be used by the patient at home. It is applied 20–30 minutes daily until healing occurs.

According to the manufacturer, the safety and effectiveness of ultrasound bone growth stimulation has not been established for the following: fracture locations other than the distal radius or tibial diaphysis; fractures with post-reduction displacements of more than 50%; fractures that are open Grade II or III; fractures that require surgical intervention or external fixation; or for fractures that are not sufficiently stable for closed reduction and cast immobilization. Individuals who are not skeletally mature or who are pregnant/nursing are not candidates for this therapy. Ultrasound bone growth stimulation is also not indicated for fractures related to bone pathology or malignancy (Exogen, 2000).

U.S. Food and Drug Administration (FDA): Ultrasound bone growth stimulators are premarket approved (PMA) by the U.S. Food and Drug Administration (FDA) as class III devices. Class III devices are the most regulated devices by the FDA and require data from clinical studies to ensure safety and effectiveness. Several devices have received approval from the FDA. The Sonic Accelerated Fracture Healing System (SAFHS[®]) Model 2A was granted approval by the FDA on October 5, 1994, for accelerating the time to a healed fracture for fresh, closed Colles' fractures and fresh, closed or open tibial diaphysis fractures in skeletally mature individuals. On July 7, 1995, the FDA granted approval for the SAFHS Model 2A to be used by patients at home. The SAFHS Model 2000, also known as Exogen 2000[®] (Smith & Nephew, Inc., Memphis, TN) received FDA premarket approval (PMA) in 2000 for treatment of fractures through bone growth stimulation. On February 22, 2000, the FDA granted approval for the SAFHS 2000 and the Exogen 2000 for the noninvasive treatment of established nonunions. Device labeling excludes nonunions of the skull or vertebrae (FDA, 2000).

The manufacturer of the Exogen device maintained a patient registry with physician input regarding information pertaining to the initial fracture, patient characteristics, and final outcomes from use of the device. According to Rubin et al. (2001), the device was prescribed for more than 22,300 patients, of which 10,050 had a 91% rate of healing, an average healing time of 144 days, and an average fracture age of 168 days from the date of initial injury. At the time of the author's publication, a total of 1470 patients were lost to follow-up, 1640 patients withdrew from the program or were noncompliant, and 9100 were still receiving treatment. Moreover, fractures other than the radius or tibia were also treated with ultrasound in the registry and demonstrated improved healing times.

The 2000 FDA approval for the noninvasive treatment of nonunion was based on data from the registry and unpublished retrospective case series.

Literature Review: Evidence in the published, peer-reviewed scientific literature, some in the form of randomized trials, indicates that ultrasound has been shown to be effective in promoting healing of fresh fractures of the tibia (Heckman, et al., 1994) and radial fractures (Kristiansen, et al., 1997). There is also evidence that ultrasound is effective in accelerating healing for nonunion and delayed union of various other fracture sites including the tibia, femur, scaphoid, humerus, clavicle, and metatarsals and metacarpals (Nolte, et al., 2001; Rubin, et al., 2001).

Low-intensity pulsed ultrasound has not been shown to have significant effects on intact bone for prevention of postmenopausal bone loss in the distal radii. Leung et al. (2004) conducted a randomized controlled prospective trial to evaluate the potential effect of low-intensity pulsed ultrasound on intact bone for prevention of postmenopausal bone loss in the distal radius (n=20). Results of this study showed that the rate of bone change (trabecular bone mineral density and integral bone mineral density) did not significantly differ between the site treated with low-intensity pulsed ultrasound and the contralateral control at either follow-up. Also, during the follow-up, bone mineral density did not change significantly in the contralateral control site.

Nolte et al. (2001) conducted a controlled clinical trial evaluating low-intensity ultrasound for the treatment of fracture nonunion. Twenty-nine cases with fracture nonunion of the tibia, femur, radius/ulna, scaphoid, humerus, metatarsal, and clavicle were included in the study. The initial fracture care consisted of conservative treatment in eight cases and of surgical care in 21 cases. Ultrasound treatment was started an average of 61 weeks post-fracture treatment. The study demonstrated 25 of the 29 cases healed in an average of 22 weeks.

In a published review, Rubin et al. (2001) reported there is a large body of evidence supporting fracture healing augmented by low-intensity ultrasound. The authors reviewed several studies evaluating the use of ultrasound for delayed union and nonunion of various sites such as the scaphoid, clavicle, ulna, femur and metatarsals and concluded that the data suggest ultrasound is a reasonable treatment for fractures that have delayed healing, for those not yet on a normal course of healing, and for those patients whose metabolic status may be compromised by disease or medication.

Cook et al. (1997) conducted a randomized, controlled trial of low-intensity ultrasound in the healing of tibia and distal radius fracture in patients who smoke (tibial fracture n=67, radial fracture n=63). The time needed for healing of a tibial fracture in patients who smoked and were treated with the active ultrasound device was reduced 72 days, or more than 43% less than that of patients who smoked and were treated with a placebo-control device.

Electrical Bone Growth Stimulators

Electrical bone growth stimulators fall into one of three categories: noninvasive, invasive or semi-invasive. A noninvasive device utilizes treatment coils situated around the fracture site and an external power supply. Noninvasive devices deliver current by way of capacitive coupling, pulsed electromagnetic field (PEMF) or combined electromagnetic field (CMF) technology. Invasive and semi-invasive devices are also referred to as implantable devices and use a direct current delivered directly to the fracture site by way of implantable electrodes. Electrical fields that are applied to the fracture site aid bone healing by enhancing the normal electrical potentials and upregulating the cellular processes involved in bone formation. Callus vascularization, cell proliferation, matrix protein synthesis, and secretion of growth factors may all be enhanced by electrical stimulation (AHRQ, 2005).

Indications for use are based upon FDA labeling for specific devices and evidence in the peer-reviewed published scientific literature. Most studies evaluating the use of electrical stimulation have focused on nonunion and spinal fusion; the use of these devices in humans for the treatment of fresh fractures has not been clearly demonstrated (Moucha, Einhorn, 2003). Furthermore, data to support improved clinical outcomes for patients undergoing spinal fusion and who are not considered high risk for failed fusion is inadequate. A majority of the patients involved in clinical trials, utilizing the device as an adjunct to spinal fusion, were considered high risk for failed fusion. Although indications vary among devices, electrical bone growth stimulation is not indicated for nonunion fractures where the bones are not aligned or a synovial pseudarthrosis exists, when the bone gap is more than one centimeter or greater than one-half the diameter of the bone, and for patients who are unable to be compliant with appropriate use of the device or treatment regimens.

The safety and effectiveness of electrical bone growth stimulation has not been established in bone pathology such as osteomyelitis, spondylitis, Paget's disease, metastatic cancer, advanced osteoporosis or arthritis, or for

avascular or necrotic bone tissues. Patients lacking skeletal maturity, pregnant women and patients with demand pacemakers or implantable defibrillators are not candidates for electrical bone growth stimulator therapy. Fixation devices made from magnetic materials may compromise the effects of electric bone growth stimulators (Orthofix 2005).

Noninvasive Bone Growth Stimulators: Noninvasive bone growth stimulators use inductive and conductive methods to deliver a broad, uniform electric field, pulse electromagnetic field (PEMF), or combined electromagnetic (CMF) field to the fracture site via treatment coils or disks placed on the skin and attached to an external power supply.

Direct electrical current has been shown to have a stimulatory effect on bone formation. The bulk of the scientific evidence demonstrating the efficacy of noninvasive electrical bone growth stimulation addresses its use for nonunion fractures in long bones or as an adjunct to spinal fusion.

U.S. Food and Drug Administration (FDA): Noninvasive electrical bone growth stimulators are class III devices approved by the FDA through the premarket approval process. FDA-approved devices include: OL 1000[®] and SpinaLogic Bone Growth Stimulator[®] (Regentek, a division of dj Orthopedics, LLC (formerly OrthoLogic, Tempe, AZ); Physio-Stim Lite[®], Spinal-Stim Lite[®] (Orthofix, Inc., Richardson, TX); EBI Bone Healing System[®], SpinalPak[®], and OrthoPak[®] (Bioelectron, a subsidiary of Electro-Biology, Inc., Parsippany, NJ) (FDA, 2001). FDA labeling and indications for specific devices vary. For example, the EBI Bone Healing System is indicated for the treatment of fracture nonunion, failed fusions, and congenital pseudoarthrosis of the appendicular skeletal system; SpinalPak is indicated as an adjunct electrical treatment to primary lumbar spinal fusion surgery for one or two levels.

Literature Review: Evidence in the published scientific literature in the form of meta-analysis, randomized clinical trials, and both prospective and retrospective case series suggests there is a favorable impact on bone healing with the use of noninvasive electrical bone growth stimulators (Akai, et al., 2002; Goodwin, et al., 1999; Abdeed, et al., 1998; Scott, et al., 1994). In a meta-analysis of available literature, Akai et al. (2002) examined whether electrical stimulation (i.e., direct current, PEMF, capacitive coupling) has a specific effect on spinal fusion. The authors reviewed a total of five randomized controlled trials (RCTs) that assessed healing of spinal fusion and noted that the methodological quality score of each trial showed wide flaws. Excluding one trial with the lowest score, the combined results of four trials, whose major endpoints were the success rate of the fusion, revealed a statistically significant effect of electrical stimulation with various techniques. Level 1

Goodwin et al. (1999) conducted a randomized, double-blind prospective comparison with a placebo control to evaluate the effect of noninvasive capacitively-coupled electrical stimulation (CCEST) on the success rate of lumbar spine fusion surgery, and to compare active with placebo stimulators as adjuncts to contemporary fusion techniques. The results of this study demonstrated that for the 179 patients who completed treatment and evaluation, the overall protocol success rate (both clinical and radiographic results rated as successes) was 84.7% for the active patients and 64.9% for the placebo patients. This difference is highly significant according to the Yates corrected chi-square test ($p=0.0043$). Best improvements in patient outcomes (20% or greater success rate) occurred when active stimulation was used in conjunction with posterolateral fusion ($p=0.006$) and when internal fixation also was incorporated ($p=0.013$).

Abdeed et al. (1998) conducted an uncontrolled, prospective descriptive study to determine the extent to which CCEST applied at a long bone fracture site can promote healing of nonunited fractures. Sixteen patients with nonunion of long bone fractures (i.e., radius, tibia, ulnar or femur) of 9–76 months were treated with CCEST. The device was used for up to 30 weeks; if no healing occurred by this time it was removed and considered to have failed. The results indicated that 11 of the nonunions achieved union at an average of 15 weeks of stimulation. The only significant factor determining the success of healing was the distance between the plates; a distance of 80 mm or less resulted in healing in all cases.

Invasive Bone Growth Stimulators: Invasive bone growth stimulators are implanted devices that deliver electrical energy to a nonhealing fracture or bone fusion site. The goal is to induce osteogenesis, stimulate bone growth and promote fracture healing. Invasive and semi-invasive devices use direct current that is delivered directly to the fracture site by way of an implanted electrode. The advantage of invasive electric bone growth systems over noninvasive systems is that a constant current is delivered to the fracture site without the concerns for patient compliance or cooperation.

Semi-invasive direct current stimulation uses a cathode implanted in the cortex of one end of the nonunion site and attached to an external power supply. An anode attached to the skin completes the electrical circuit. Invasive direct current stimulation involves threading the cathode through or around the bone with the anode and power supply implanted in the surrounding soft tissue.

Implantable stimulators are indicated for nonunion of the tibia, femur and humerus. Invasive electrical bone stimulators have also been shown to be effective in promoting bone healing in high-risk individuals undergoing spinal fusion. A high-risk patient is one with a prior fusion failure, who is undergoing a multi-level fusion, or a patient at risk for poor healing such as one who smokes, is obese or has diabetes.

U.S. Food and Drug Administration (FDA): Two FDA-approved implantable bone growth stimulators include the OsteoGen™ and the SpF® Implantable Spine Fusion Stimulator, manufactured by EBI (EBI L.P., Parsippany, NJ). The OsteoGen™ and OsteoGen™-D are designed for the treatment of fracture nonunion, with the latter model indicated only for use in multiple nonunions or severely comminuted fractures that require more than one electrode to facilitate treatment. Four models of the SpF Implantable Spine Fusion Stimulator are available. The SpF®-2T and SpF®-4T are indicated for fusion of one or two levels, while the SpF®-XL and SpF®-XL IIb are indicated for fusion of three or more levels. In 2003, EBI added the SpF®-PLUS to their product range. The FDA has also approved the Zimmer Direct Current Bone Growth Stimulator (Zimmer, Inc., Warsaw, IN) for the treatment of fracture nonunions (FDA, 2004).

Literature Review: Several of the studies evaluating electrical bone growth stimulators for the treatment of nonunion of long bones are in the form of case series, comparative trials with historical controls, or uncontrolled trials. Authors generally agree that electrical stimulation appears to be as effective as bone grafting and standard fixation methods for nonunion of fractures.

In June 2005, the American Association of Neurological Surgeons/Congress of Neurological Surgeons Joint Section on Disorders of the Spine and Peripheral Nerves published a practice guideline for the performance of fusion procedures for degenerative disease of the lumbar spine (Resnick, et al., 2005). Specific surgical treatments were analyzed and recommendations provided. The authors recommended treatment guideline supports the use of direct current stimulation (DCS) or capacitive coupling stimulation (CCS) as an adjunct to spinal fusion in patients who are at high risk for failure following posterior lumbar fusion, and pulsed electromagnetic field stimulation in similar patients treated with lumbar interbody fusion procedures. The authors reported that much of the published studies have methodological flaws preventing them from being considered Class I evidence regarding the use of bone stimulators for the promotion of bone healing following lumbar fusion. There is Class II and Class III evidence to support the use of DCS or CCS for enhancing fusion rates in high-risk patients undergoing lumbar posterior-lateral fusion. The evidence is not consistent in patients who are not high-risk or in patients treated with interbody fusion. Furthermore, pulsed electromagnetic field stimulation has been shown to promote arthrodesis following interbody fusion, although the evidence is limited to Class II and Class III medical evidence. Earlier clinical studies published in the peer-reviewed, scientific literature support higher fusion rates and clinical success with the use of electrical bone stimulators as an adjunct to spinal fusion (Kucharzyk, et al., 1999; Rogozinski, et al., 1996).

Additionally, Hotta (1994) completed a health technology review for the Agency for Health Care Policy and Research (AHCPR), currently referred to as the Agency for Healthcare Research and Quality (AHRQ), and determined that direct electrical current stimulates bone formation and that it has been used as a standard of care in the treatment of long bone fractures that have failed to fuse. Furthermore, this group of authors reported that direct current stimulation may play a similar role in spinal fusion, especially in patients who have had fusion failures or who are at high risk for fusion failures. The available data appear to suggest that an implantable bone-growth stimulator may be a useful adjunct that could enhance the probability of fusion success in patients who have had previous fusion failure or need extensive bone grafting for multiple level fusion. The authors acknowledged that there is insufficient data to support use of an implantable bone-growth stimulator in high-risk patients such as those who have spondylolisthesis, who are obese, or are smokers.

Summary

There is sufficient evidence in the peer-reviewed scientific literature to support the safety and efficacy of ultrasound bone growth therapy in patients with fresh fractures of the distal radius and the tibial diaphysis, when the patients have skeletal maturity, and when the therapy is used as an adjunct to closed reduction and cast

immobilization, or for nonunion of bones other than skull or vertebrae in skeletally mature individuals. There is also some evidence to support ultrasound stimulation may enhance healing of fractures that are high risk for delayed union or nonunion, in addition to stress fracture nonunion.

There is sufficient evidence in the peer-reviewed scientific literature to support the efficacy of electrical bone growth stimulation in the healing of an established nonunion of stress fractures, and for nonunion acquired secondary to trauma, excluding all vertebrae and flat bones, where the width of the nonunion defect is less than one-half the width of the bone to be treated. Literature supports the safety and efficacy of invasive or noninvasive bone growth stimulation devices in the adjunctive treatment of patients with prior spinal fusion failure or who are undergoing a multi-level fusion, or in patients who have one or more risk factors for nonhealing such as: smoking, obesity, diabetes, renal disease, or other metabolic disease where bone healing is poor.

There is insufficient evidence in the peer-reviewed, published scientific literature to support the clinical utility of bone growth stimulation for the treatment of any of the following nonunion conditions:

- fresh fractures (other than when using ultrasound bone stimulation for the tibia, radius or other high-risk fractures)
- toe fractures
- sesamoid fractures
- avulsion fractures
- osteochondral lesions
- displaced fractures with malalignment
- synovial pseudarthrosis
- the bone gap is either > 1 cm or > one-half the diameter of the bone

Coding/Billing Information

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

Covered when medically necessary:

CPT®* Codes	Description
20974	Electrical stimulation to aid bone healing; non invasive (nonoperative)
20975	Electrical stimulation to aid bone healing; invasive (operative)
20979	Low intensity ultrasound stimulation to aid bone healing, noninvasive (nonoperative)

HCPCS Codes	Description
E0747	Osteogenesis stimulator; electrical, noninvasive, other than spinal applications
E0748	Osteogenesis stimulator; electrical, noninvasive , spinal applications
E0749	Osteogenesis stimulator; electrical, surgically implanted
E0760	Osteogenesis stimulator, low intensity ultrasound, noninvasive

ICD-9-CM Diagnosis Codes	Description
250.00- 250.93	Diabetes mellitus
275.40	Unspecified disorder of calcium metabolism
275.41	Hypocalcemia
277.9	Unspecified disorder of metabolism
278.00	Obesity, unspecified

588.1	Nephrogenic diabetes insipidus
593.9	Unspecified disorder of kidney and ureter
733.82	Nonunion of fracture
733.91	Arrest of bone development or growth
733.93	Stress fracture of tibia or fibula
733.94	Stress fracture of the metatarsals
813.00	Unspecified fracture of radius and ulna, upper end of forearm, closed
813.41	Closed Colles' fracture
814.00	Unspecified closed fracture of carpal bone
814.10	Unspecified open fracture of carpal bone
813.42	Other closed fractures of distal end of radius (alone)
815.00 - 815.19	Fracture of metacarpal bones
823.00	Closed fracture of upper end of tibia
823.10	Open fracture of upper end of tibia
823.20	Closed fracture of shaft of tibia
823.30	Open fracture of shaft of tibia
823.80	Closed fracture of unspecified part of tibia
823.90	Open fracture of unspecified part of tibia
825.25	Closed fracture of metatarsal bone(s)
825.35	Open fracture of metatarsal bone(s)
996.49	Other mechanical complication of other internal orthopedic device, implant, and graft
V15.82	Personal history of tobacco use, presenting hazards to health

Experimental/Investigational/Unproven/Not Covered:

ICD-9-CM Diagnosis Codes	Description
733.90	Disorder of bone and cartilage, unspecified
733.95	Stress fracture of other bone
826.0-826.1	Fracture of one or more phalanges of foot
	Multiple/Varied

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

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	4/15/2008	0084	Bone Growth Stimulators: Electrical (Invasive, Noninvasive), Ultrasound
Great-West Healthcare	7/19/2007	95.224.07	Bone Growth Stimulators, Electrical
	7/19/2007	95.225.07	Bone Growth Stimulators, Ultrasound

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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.