



CIGNA MEDICAL COVERAGE POLICY

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

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

**Effective Date4/15/2011
Next Review Date4/15/2012
Coverage Policy Number0084**

Table of Contents

Coverage Policy	1
General Background	3
Coding/Billing Information	6
References	10
Policy History	14

Hyperlink to Related Coverage Policies

Bone Graft Substitutes for Use in Bone Repair
Hyperbaric Oxygen Therapy, Systemic and Topical
Ilizarov Procedure
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. Please note, the terms of a customer'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 customer'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 customer'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 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 ©2011 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.

ULTRASOUND BONE GROWTH STIMULATOR

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

- 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 healing 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)
- Nonunion of fractures when ALL of the following criteria are met:
 - 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)
 - fracture gap is ≤ 1 cm
 - nonunion is not related/due to malignancy
 - it is \geq three months from the date of injury or initial treatment
 - 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
 - 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 does not cover an ultrasound bone growth stimulator for ANY other indication, including the following, because it is considered experimental, investigational or unproven:

- as part of the acute treatment for any fracture requiring open reduction and internal fixation (ORIF)
- fresh fractures (other than for the above listed indications)

ELECTRICAL BONE GROWTH STIMULATOR

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

- Treatment is for a fracture nonunion, and ALL of the following criteria are met:
 - 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
 - fracture gap is ≤ 1 cm
 - 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.
- Failed fusion of a joint other than the spine when a minimum of three months has elapsed since the time of initial surgery.
- 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
 - following multi-level fusion (i.e., > 1 level)
 - 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 an electrical bone growth stimulator for ANY other indication, including the following because it is considered experimental, investigational or unproven:

- for the treatment of fresh fractures
- when used to enhance healing of fractures that are considered to be at high risk for delayed union or nonunion (e.g., smoking, diabetes, renal disease, or other metabolic disease where bone healing is likely to be compromised)
- for the treatment of pars interarticularis defect (i.e., spondylolysis, spondylolisthesis)

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

- toe fractures
- sesamoid fractures
- avulsion fractures
- osteochondral lesions
- displaced fractures with malalignment
- synovial pseudoarthrosis
- the bone gap is either > 1cm or > one-half the diameter of the bone

General Background

Bone healing is a complex process dependent on a variety of factors. The rate of bone repair and composition of tissue varies depending on type of bone fractured, the extent of the bone and soft tissue damage, the adequacy of the blood supply, and the degree of separation between bone ends. The individual's general health and nutritional status also play a significant role in bone healing. The presence of infection may adversely affect healing. Diminished blood flow to the fracture site will often suppress the healing response; factors that can cause diminished blood flow include heavy smoking, obesity and malnutrition, diabetes, alcoholism, peripheral vascular disease, increasing age, and the use of some medications such as steroids. 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).

Bones heal at different rates, however approximately five to ten percent of fractures result in nonunion or delayed union. 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.

Nonunion of long bone fractures (i.e., clavicle, humerus, radius, ulna, femur, tibia, fibula, metatarsals, metacarpals) is considered to exist when a minimum of two sets of radiographs, obtained prior to starting treatment, separated by a minimum of 90 days, show no evidence of fracture healing between the two sets of radiographs (Centers for Medicare and Medicaid Services [CMS], 2000). Fracture nonunion of short bones, such as the carpal and tarsal bones (e.g., talus, scaphoid, calcaneous) should be clearly evident throughout the entire body of the bone. Methods available to evaluate healing and nonunion of bone 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 confirm nonunion.

Some types of bones are more likely to have poor healing responses. 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).

Treatment of nonunion may involve a variety of invasive and noninvasive interventions which include 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 may be used instead of or in addition to other interventions to promote bone healing. Ultrasound and electrical devices are considered standard of care in the treatment of long bone fractures that have failed to fuse. Ultrasound bone growth stimulating devices are also recommended for healing of fresh fractures. There is some data to suggest bone stimulation devices have been effective for treatment of stress fracture nonunion (DiGiovanni, et al., 2003; Beck et al., 2008). Both invasive and noninvasive electrical devices are accepted as an adjunctive treatment to spinal fusion when patients are at high risk of fusion failure. Implantable devices may also be used as an adjunct to planned surgical treatment of an established nonunion (e.g., bone grafts, internal/external fixation).

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. Smith and Nephew, Inc. (Nashville, TN) received the original PMA from the FDA for the Sonic Accelerated Fracture Healing System (SAFHS®) Model 2A. However, since that time supplemental approvals have been granted with various changes incorporated into the device. The device is now known as the Exogen device (i.e., 2000, 3000, 4000). Indications for intended use, based on FDA labeling for the specific devices and evidence in the peer-reviewed published scientific literature, include fresh closed Colles' fracture, fresh closed or open tibial diaphysis fractures and nonunions. Device labeling excludes nonunions of the skull or vertebrae (FDA, 2000).

Literature Review: Evidence in the published, peer-reviewed scientific literature, including a patient registry, indicates that ultrasound has been shown to be effective in promoting healing of fresh fractures of the tibia and radial fractures (Heckman, et al., 1994; Kristiansen, et al., 1997; Cook, 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). In a published review, Rubin et al. (2001) acknowledged 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. Some clinical outcomes are mixed but there is evidence to support the effectiveness of ultrasound when used for treatment of stress fractures, such as those of the tibia shaft (Bederka, Amendola, 2009). Published systematic reviews and technology assessments have concluded the evidence is moderate to low quality and conflicting, however the evidence does continue to support efficacy for these uses (Agency for Healthcare Research and Quality

[AHRQ], 2005; Busse, et al., 2009; Dijkman, et al., 2009; Washington State Health Care Authority, 2009). One published meta-analysis found a statistically significant pooled mean reduction in radiographic healing time of 33.6% with the use of ultrasound stimulation devices overall (Busse, et al., 2009). A systematic review noted an average healing rate of 87% among trials evaluating low intensity ultrasound for treatment of nonunion (Dijkman, et al., 2009). 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).

Electrical Bone Growth Stimulators

Electrical bone growth stimulators fall into one of three categories: noninvasive, invasive or semi-invasive. 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. Nevertheless 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, the use of these devices in humans for the treatment of fresh fractures has not been clearly demonstrated (Moucha, Einhorn, 2003). Evidence evaluating the use of electrical stimulation devices for the treatment of pars fractures (i.e., spondylolisthesis, spondylolysis) is lacking; published evidence consists of few small retrospective case series and case reports (Lauerman, Zavata, 2009; Stasinopoulos D, 2004; Fellander Tsai, Micheli, 1998). 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. In contrast to ultrasound bone stimulation devices, there is insufficient evidence to support the effectiveness of these devices when used to enhance healing of fractures that are considered to be at high risk for delayed union or nonunion.

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. Several FDA-approved devices are available some which include the following: 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 technology assessments, meta-analysis, randomized clinical trials, and both prospective and retrospective case series indicates there is a favorable impact on bone healing with the use of noninvasive electrical bone growth stimulators (Scott, et al., 1994; Abdeed, et al., 1998; Goodwin, et al., 1999; Akai, et al., 2002; AHRQ, 2005; Washington State Healthcare Authority, 2009; Gupta, et al, 2009).

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): There are many FDA approved invasive bone growth stimulator devices. Two FDA-approved implantable devices 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. Published technology assessments also support efficacy of these devices for healing nonunion fractures (AHRQ, 2005; Washington State Healthcare Authority, 2009). 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 which supports the use of electrical bone growth stimulators as an adjunct to spinal fusion (Resnick, et al., 2005). Furthermore, other clinical studies published in the peer-reviewed, scientific literature (Rogozinski, et al., 1996; Kucharzyk, et al., 1999) and a health technology assessment (Hotta, 1994) support higher fusion rates and clinical success with the use of electrical bone stimulators as an adjunct to spinal fusion.

Summary

Evidence in the peer-reviewed published scientific literature supports the safety and efficacy of ultrasound and electrical bone growth stimulation devices for the treatment of bone fracture, joint fusion and nonunion. When used for these indications, data suggest these devices induce osteogenesis, stimulate bone growth, and promote healing of bone.

Evidence in the peer-reviewed, published scientific literature is lacking and does not support the clinical utility of bone growth stimulation for the treatment of any other indication.

Coding/Billing Information

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

Ultrasound Bone Growth Stimulators

Covered when medically necessary:

CPT®* Codes	Description
20979	Low intensity ultrasound stimulation to aid bone healing, noninvasive (nonoperative)

HCPCS Codes	Description
E0760	Osteogenesis stimulator, low intensity ultrasound, noninvasive

ICD-9-CM Diagnosis Codes	Description
733.82	Nonunion of fracture
733.93	Stress fracture of tibia or fibula
733.94	Stress fracture of metatarsals
733.96	Stress fracture of femoral neck
733.97	Stress fracture of shaft of femur
733.98	Stress fracture of pelvis
813.00- 813.08	Unspecified fracture of radius and ulna, upper end of forearm, closed
813.20- 813.23	Fracture of radius and ulna, shaft, closed
813.40- 813.47	Fracture of radius and ulna, lower end, closed
813.80- 813.83	Fracture of radius and ulna, unspecified part, closed
814.00- 814.09	Fracture of carpal bone(s), closed
816.00- 816.03	Fracture of one or more phalanges of hand, closed
817.0	Multiple fractures of hand bones
823.00- 823.02	Fracture of tibia and fibula, upper end, closed
823.10- 823.12	Fracture of tibia and fibula, upper end, open
823.20- 823.22	Fracture of tibia and fibula, shaft, closed
823.30- 823.32	Fracture of tibia and fibula, shaft, open
823.80- 823.82	Fracture of tibia and fibula, unspecified part, closed
823.90- 823.92	Fracture of tibia and fibula, unspecified part, open
825.20- 825.25	Fracture of other tarsal and metatarsal bones, closed

Experimental/Investigational/Unproven/Not Covered:

ICD-9-CM Diagnosis Codes	Description
170.4-170.9	Malignant neoplasm of bones
198.5	Secondary malignant neoplasm of bone and bone marrow
733.10- 733.19	Pathologic fracture
733.42	Aseptic necrosis of head and neck of femur

733.90	Disorder of bone and cartilage, unspecified
733.95	Stress fracture of other bone
733.99	Other and unspecified disorders of bone and cartilage; other
800.00-804.99	Fracture of skull
805.00-805.08	Fracture of vertebral column without mention of spinal cord injury; cervical, closed
805.10-805.18	Fracture of vertebral column without mention of spinal cord injury; cervical, open
805.20-805.28	Fracture of vertebral column without mention of spinal cord injury; dorsal (thoracic),closed
805.30-805.38	Fracture of vertebral column without mention of spinal cord injury; dorsal (thoracic),open
805.40-805.48	Fracture of vertebral column without mention of spinal cord injury; lumbar, closed
805.50-805.58	Fracture of vertebral column without mention of spinal cord injury; lumbar, open
805.60-805.68	Fracture of vertebral column without mention of spinal cord injury; sacrum and coccyx, closed
805.70-805.78	Fracture of vertebral column without mention of spinal cord injury; sacrum and coccyx, open
812.10-812.19	Open fracture of upper end of humerus
812.30-812.31	Open fracture of shaft or unspecified part of humerus
812.50-812.59	Open fracture of lower end of humerus
813.10-813.18	Open fracture of upper end of radius
813.30-813.33	Open fracture of shaft of radius and ulna
813.50-813.53	Open fracture of lower end of radius and ulna
813.90-813.93	Open fracture of unspecified part of radius with ulna
814.10-814.19	Open fractures of carpal bones
815.10-815.19	Fracture of metacarpal bone(s), open
821.0-821.11	Open fracture of shaft or unspecified part of femur
821.30-821.39	Open fracture of lower end of femur
824.1	Open fracture of medial malleolus
824.3	Open fracture of lateral malleolus
824.5	Open bimalleolar fracture
824.7	Open trimalleolar fracture
824.9	Unspecified open fracture of ankle
825.33	Fracture of tarsal and other metatarsal bones open, cuboid
825.35	Fracture of tarsal and other metatarsal bones open, metatarsal bone(s)
826.0-826.1	Fracture of one or more phalanges of foot
996.67	Infection and inflammatory reaction due to other internal orthopedic device, implant, and graft
996.78	Other complications due to internal orthopedic device, implant and graft
	All other codes

Electrical Bone Growth Stimulators

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)

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

ICD-9-CM Diagnosis Codes	Description
013.40 – 013.46	Tuberculoma of spinal cord
013.50 – 013.56	Tuberculous abscess of spinal cord
015.00- 015.06	Tuberculosis of vertebral column
733.82	Nonunion of fracture
733.93	Stress fracture of tibia or fibula
733.94	Stress fracture of metatarsals
733.96	Stress fracture of femoral neck
733.97	Stress fracture of shaft of femur
733.98	Stress fracture of pelvis
737.30	Scoliosis (and kyphoscoliosis), idiopathic
737.34	Thoracogenic scoliosis
737.39	Kyphoscoliosis and scoliosis, other
737.43	Scoliosis associated with other condition
806.4	Closed fracture of lumbar spine with spinal cord injury
806.5	Open fracture of lumbar spine with spinal cord injury
V45.4	Arthrodesis status

Experimental/Investigational/Unproven/Not Covered:

ICD-9-CM Diagnosis Codes	Description
170.4-170.9	Malignant neoplasm of bones
198.5	Secondary malignant neoplasm of bone and bone marrow
733.10- 733.19	Pathologic fracture
733.42	Aseptic necrosis of head and neck of femur
733.90	Disorder of bone and cartilage, unspecified
733.95	Stress fracture of other bone
733.99	Other and unspecified disorders of bone and cartilage; other
800.00- 804.99	Fracture of skull
805.00- 805.08	Fracture of vertebral column without mention of spinal cord injury; cervical, closed

805.10-805.18	Fracture of vertebral column without mention of spinal cord injury; cervical, open
805.20-805.28	Fracture of vertebral column without mention of spinal cord injury; dorsal (thoracic),closed
805.30-805.38	Fracture of vertebral column without mention of spinal cord injury; dorsal (thoracic),open
805.40-805.48	Fracture of vertebral column without mention of spinal cord injury; lumbar, closed
805.50-805.58	Fracture of vertebral column without mention of spinal cord injury; lumbar, open
805.60-805.68	Fracture of vertebral column without mention of spinal cord injury; sacrum and coccyx, closed
805.70-805.78	Fracture of vertebral column without mention of spinal cord injury; sacrum and coccyx, open
815.10-815.19	Fracture of metacarpal bone(s), open
825.33	Fracture of tarsal and other metatarsal bones open, cuboid
825.35	Fracture of tarsal and other metatarsal bones open, metatarsal bone(s)
826.0-826.1	Fracture of one or more phalanges of foot
996.67	Infection and inflammatory reaction due to other internal orthopedic device, implant, and graft
996.78	Other complications due to internal orthopedic device, implant and graft
	All other codes

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

References

1. Abeed R, Naseer M, Abel E. Capacitively coupled electrical stimulation treatment: results from patients with failed long bone fracture unions. J Orth Trauma.1998 Sep -Oct;12(7):510-3.
2. Akai M, Kawashima N, Kimura T, Hayashi K. Electrical stimulation as an adjunct to spinal fusion: a meta-analysis of controlled clinical trials. Bioelectromagnetics. 2002 Oct;23(7):496-504.
3. Agency for Healthcare Research and Quality (AHRQ). The role of bone growth stimulating devices and orthobiologics in healing nonunion fractures. Technology assessment program. Prepared by ECRI Evidence-based Practice Center (EPC).September 21, 2005. Accessed February 28, 2011. Available at URL address: <http://www.ahrq.gov/clinic/techix.htm#completed>
4. American Academy of Orthopedic Surgeons (AAOS). Nonunions. March 2005. Updated September 2007. Accessed February 28, 2011. Available at URL address: http://orthoinfo.aaos.org/fact/thr_report.cfm?Thread_ID=478&topcategory=General%20Information
5. American Academy of Orthopedic Surgeons (AAOS).Physical fields. October 2002. Accessed February 28, 2011. Available at URL address: <http://orthoinfo.aaos.org/topic.cfm?topic=A00279>
6. Beck BR, Matheson GO, Bergman G, Norling T, Fredericson M, Hoffman AR, Marcus R. Do capacitively coupled electric fields accelerate tibial stress fracture healing? A randomized controlled trial. Am J Sports Med. 2008 Mar;36(3):545-53. Epub 2007 Nov 30.
7. Bederka B, Amendola A. Stress fractures of the leg. In : DeLee: DeLees and Drez's Orthopaedic Sports Medicine, 3rd ed. Ch 24. Copyright © 2009 Saunders.
8. Benazzo F, Mosconi M, Beccarisi G, Galli U. Use of capacitive coupled electric fields in stress fractures in athletes. Clin Orthop Relat Res. 1995 Jan;(310):145-9.

9. Bora F, Osterman A, Woodbury D, Brighton C. Treatment of nonunion of the scaphoid by direct current. *Orthop Clinics of N Am*. 1984 Jan;15(1):107-113.
10. Busse J, Bhandari M, Kulkarni A, Tunks E. The effect of low-intensity pulsed ultrasound therapy on time to fracture healing: a meta-analysis. *CMAJ* 2002 Feb;166(4):437-41.
11. Busse JW, Kaur J, Mollon B, Bhandari M, Tornetta P 3rd, Schünemann HJ, Guyatt GH. Low intensity pulsed ultrasonography for fractures: systematic review of randomised controlled trials. *BMJ*. 2009 Feb 27;338:b351.
12. Cook S, Ryaby J, McCabe J, Frey J, Heckman J, Kristiansen T. Acceleration of time and distal radius fracture healing in patients who smoke. *Clin Orthop* 1997 Apr;(337):198-207.
13. Centers for Medicare and Medicaid Services. National Coverage Policy Revision. Electrical stimulation for fracture healing (CAG-00022). Decision Memorandum. July 2000.
14. Coords M, Breitbart E, Paglia D, Kappy N, Gandhi A, Cottrell J, Cedeno N, Pounder N, O'Connor JP, Lin SS. The effects of low-intensity pulsed ultrasound upon diabetic fracture healing. *J Orthop Res*. 2011 Feb;29(2):181-8. doi: 10.1002/jor.21223.
15. DiGiovanni CW, Benirschke SK, Hansen ST. Stress fractures. In: Browner BD, Jupiter JB, Levine AM, Trafton PG, editors; *Browner: Skeletal Trauma: Basic Science, Management, and Reconstruction*, 3rd ed., Copyright © 2003. Ch 60 Foot Injuries.
16. Dijkman BG, Sprague S, Bhandari M. Low-intensity pulsed ultrasound: Nonunions. *Indian J Orthop*. 2009 Apr;43(2):141-8.
17. EBI Medical. Implantable Spinal Fusion Stimulator. Accessed February 26, 2008. Available at URL address: <http://www.ebimedical.com/products/detail.cfm?p=090300>
18. ECRI Institute. Hotline Response [database online].Plymouth Meeting (PA): ECRI Institute; 2008, Aug 22. Ultrasonic bone growth stimulation for fracture healing. Available at URL address: <http://www.ecri.org>
19. ECRI Institute. Hotline Response [database online].Plymouth Meeting (PA): ECRI Institute; 2006, Nov 22. Electrical bone growth stimulation for the lower leg and long bones. Available at URL address: <http://www.ecri.org>
20. ECRI Institute. Hotline Response [database online].Plymouth Meeting (PA): ECRI Institute; 2007, Jan 29. Electrical bone growth stimulation to enhance cervical vertebrae fusion. Available at URL address: <http://www.ecri.org>
21. ECRI Institute. Hotline Response [database online].Plymouth Meeting (PA): ECRI Institute; 2008, Aug 18. Electrical bone growth stimulation for the wrist, ankle, and short bones. Available at URL address: <http://www.ecri.org>
22. Feingold D, Hame S. Female athlete triad and stress fractures. *Orthop Clin N Am*. 2006 Oct;37(4):575-83.
23. Fellander-Tsai L, Micheli LJ. Treatment of spondylolysis with external electrical stimulation and bracing in adolescent athletes: a report of two cases. *Clin J Sport Med*. 1998 Jul;8(3):232-4.
24. Goldstein C, Sprague S, Petrisor BA. Electrical stimulation for fracture healing: current evidence. *J Orthop Trauma*. 2010 Mar;24 Suppl 1:S62-5.
25. Goodwin C, Brighton C, Guyer R, Johnson J, Light K, Yuan H. A double blind study of capacitively coupled electrical stimulation as an adjunct to lumbar spinal fusions. *Spine* 1999 Jul;24(13):1349-56;discussion1357.

26. Gupta AK, Srivastava KP, Avasthi S. Pulsed electromagnetic stimulation in nonunion of tibial diaphyseal fractures. *Indian J Orthop.* 2009 Apr–Jun; 43(2): 156–160.
27. Heckman J, Ryaby J, McCabe J, Frey J, Kilcoyne R. Acceleration of tibial fracture-healing by noninvasive, low-intensity pulsed ultrasound. *J Bone Joint Surg.* 1994 Jan;76(1):26-34.
28. Hockenbury RT, Gruttadauria M, McKinney I. Use of implantable bone growth stimulation in Charcot ankle arthrodesis. *Foot Ankle Int.* 2007 Sep;28(9):971-6.
29. Hotta S. Electrical bone-growth stimulation and spinal fusion. Health technology assessment review No. 8. 1998. Agency for Health Care Policy and Research (AHCPR) Pub No. 94-0014. Accessed February 28, 2011. Available at URL address: <http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat6.chapter.44092>
30. Jones MH, Amendola AS. Navicular stress fractures. *Clin Sports Med.* 2006 Jan;25(1):151-8.
31. Kristiansen T, Ryaby J, McCabe J, Frey J, Roe L. Accelerated healing of distal radial fractures with the use of specific, low-intensity ultrasound. A multicenter, prospective, randomized, double-blind, placebo-controlled study. *J Bone Joint Surg.* 1997 Jul;79(7):961-73.
32. Kucharzyk D. A controlled prospective outcome study of implantable electrical stimulation with spinal instrumentation in a high-risk spinal fusion population. *Spine* 1999 Mar;24(5):465-8;discussion 469.
33. Lauerman WC, Zavata JA. Thoracolumbar injuries. In DeLee: DeLee and Drez's Orthopaedic Sports Medicine, 3rd ed. CH 16. Copyright © 2009 Saunders.
34. Leung KS, Lee WS, Tsui HF, Liu PP, Cheung WH. Complex tibial fracture outcomes following treatment with low-intensity pulsed ultrasound. *Ultrasound Med Biol.* 2004 Mar;30(3):389-95.
35. Mollon B, da Silva V, Busse JW, Einhorn TA, Bhandari M. Electrical stimulation for long-bone fracture-healing: a meta-analysis of randomized controlled trials. *J Bone Joint Surg Am.* 2008 Nov;90(11):2322-30.
36. Moucha CS, Einhorn TA. Enhancement of skeletal repair. In: Browner BD, Jupiter JB, Levine AM, Trafton PG, editors. *Browner: Skeletal Trauma: Basic Science, Management, and Reconstruction*, 3rd ed., Copyright © 2003. Chapter 22.
37. Nishihara R. The dilemmas of a scaphoid fracture: a difficult diagnosis for primary care physicians. *Hospital Physician.* 2000 Mar;24-40.
38. Nolte P, van der Krans A, Patka P, Janssen I, Ryaby J, Albers G. Low-intensity pulsed ultrasound in the treatment of nonunions. *J Trauma* 2001 Oct;51(4):693-703;discussion 702-3.
39. Nunley JA. Fractures of the base of the fifth metatarsal. The Jones fracture. *Orthop Clin North Am.* 2001 Jan;32(1):171-80.
40. Orthofix. Bone growth stimulators. *Spinal Stim.* Accessed February 28, 2011. Available at URL address: http://www.orthofix.com/products/spine_spinalstim.asp?cid=1
44. Pettine KA, Salib RM, Walker SG. External electrical stimulation and bracing for treatment of spondylolysis. A case report. *Spine (Phila Pa 1976).* 1993 Mar 15;18(4):436-9.
42. Raasch WG, Hergan DJ. Treatment of stress fractures: The fundamentals. *Clin Sports Med.* 2006 Jan;25(1):29-36.
43. Resnick DK, Choudhri TF, Dailey AT, Groff MW, Khoo L, Matz PG, et al. American Association of Neurological Surgeons/Congress of Neurological Surgeons. Guidelines for the performance of fusion

procedures for degenerative disease of the lumbar spine. Part 17: bone growth stimulators and lumbar fusion. *J Neurosurg Spine*. 2005 Jun;2(6):737-40.

44. Ricardo M. The effect of ultrasound on the healing of muscle-pediculated bone graft in scaphoid non-union. *Int Orthop*. 2006 Apr;30(2):123-7. Epub 2006 Feb 11.
45. Rogozinski A, Rogozinski C. Efficacy of implanted bone growth stimulation in instrumented lumbosacral spinal fusion. *Spine* 1996 Nov;21(21):2479-83.
46. Rubin C, Bolander M, Ryaby JP, Hadjiargyrou M. The use of low-intensity ultrasound to accelerate the healing of fractures. *J Bone Joint Surg*. 2001 Feb;83-A(2):259-70.
47. Scott G, King J. A prospective, double blind trial of electrical capacitive coupling in the treatment of nonunion long bones. *J Bone Joint Surg Am*. 1994 Jun;76(6):820-6.
48. Schofer MD, Block JE, Aigner J, Schmelz A. Improved healing response in delayed unions of the tibia with low-intensity pulsed ultrasound: results of a randomized sham-controlled trial. *BMC Musculoskelet Disord*. 2010 Oct 8;11:229.
49. Stasinopoulos D. Treatment of spondylolysis with external electrical stimulation in young athletes: a critical literature review. *Br J Sports Med*. 2004 Jun;38(3):352-4.
50. Symou E, Tsitsopoulos PP, Marinopoulos D, Tsonidis C, Anagnostopoulos I, Tsitsopoulos PD. Spondylolysis: a review and reappraisal. *Hippokratia*. 2010 Jan;14(1):17-21.
51. U.S. Food and Drug Administration. Center for Devices and Radiological Health (CDRH). Exogen 2000[®] or Sonic Accelerated Fracture healing System. Summary of safety and effectiveness. Updated November 5, 2000. Accessed February 28, 2011. Available at URL address: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/pma/pma.cfm?num=p900009s006>
52. U.S. National Cancer Institute's Surveillance, Epidemiology and End Results (SEER) Program, with Emory University, Atlanta, Georgia, U.S.A. Anatomy and physiology: classification of bones. Accessed February 28, 2011. Available at URL address: <http://training.seer.cancer.gov/anatomy/>
53. Washington State Health Care Authority. Health Technology Assessment, Bone Growth Stimulators. July 2009. Accessed February 28, 2011. Available at URL address: http://www.hta.hca.wa.gov/documents/bgs_final_report_073109_updated.pdf
54. Watanabe Y, matysushita T, Bhandari M, Zdero R, Schemitsch. Ultrasound for fracture healing: current evidence. *J Orthop Trauma*. 2010 Mar;24(3):S56-S61.
55. Wood, GW II. General principles of fracture treatment. In: Canale TS, editor. *Canale: Campbell's Operative Orthopaedics*, 10th ed., Copyright © 2003. Chapter 50. Part XV Fractures and dislocations.
56. Yan SG, Huang LY, Cai XZ. Low-intensity pulsed ultrasound: a potential non-invasive therapy for femoral head osteonecrosis. *Med Hypotheses*. 2011 Jan;76(1):4-7.
57. Young AJ, McAllister DR. Evaluation and treatment of tibial stress fractures. *Clin Sports Med*. 2006 Jan;25(1):117-28.
58. Zura RD, Sasser B, Sabesan V, Pietrobon R, Tucker MC, Olson SA. A survey of orthopaedic traumatologists concerning the use of bone growth stimulators. *J Surg Orthop Adv*. 2007 Spring;16(1):1-4.

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

"CIGNA", "CIGNA HealthCare" and the "Tree of Life" logo are registered service marks of CIGNA Intellectual Property, Inc., licensed for use by CIGNA Corporation and its operating subsidiaries. All products and services are provided by such operating subsidiaries and not by CIGNA Corporation. Such operating subsidiaries include Connecticut General Life Insurance Company, CIGNA Health and Life Insurance Company, CIGNA Behavioral Health, Inc., CIGNA Health Management, Inc., and HMO or service company subsidiaries of CIGNA Health Corporation and CIGNA Dental Health, Inc. In Arizona, HMO plans are offered by CIGNA HealthCare of Arizona, Inc. In California, HMO plans are offered by CIGNA HealthCare of California, Inc. In Connecticut, HMO plans are offered by CIGNA HealthCare of Connecticut, Inc. In North Carolina, HMO plans are offered by CIGNA HealthCare of North Carolina, Inc. In Virginia, HMO plans are offered by CIGNA HealthCare Mid-Atlantic, Inc. All other medical plans in these states are insured or administered by Connecticut General Life Insurance Company or CIGNA Health and Life Insurance Company.