



Medical Coverage Policy

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

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Related Coverage Resources

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- [Lumbar Fusion for Spinal Instability and Degenerative Disc Conditions, including Sacroiliac Fusion](#)

INSTRUCTIONS FOR USE

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Overview

This Coverage Policy addresses electrical and ultrasonic bone growth stimulators to enhance the bone healing process.

Coverage Policy

Coverage for ultrasound and noninvasive electrical bone growth stimulators varies across plans. Invasive bone growth stimulators are considered internal medical devices and, therefore, are covered under the core medical benefits of many plans. Refer to the customer's benefit plan document for coverage details.

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

ULTRASOUND BONE GROWTH STIMULATOR (HCPCS code E0760)

An ultrasound bone growth stimulator is considered 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:
 - poor blood supply due to anatomical location (e.g., scaphoid, 5th metatarsal)
 - at least one comorbidity where bone healing is likely to be compromised (e.g., smoking, diabetes, renal disease)

- 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/secondary to malignancy
 - it is ≥ 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

- Nonunion of a stress fracture when ALL of the following criteria are met:
 - it is ≥ three months from initial identification of the stress fracture
 - failure of a minimum of 90 days of conventional, nonsurgical management (e.g., rest, bracing)
 - radiograph imaging studies at least 90 days from the initial identification of the stress fracture demonstrates a fracture line that has not healed

An ultrasound bone growth stimulator for ANY other indication, including ANY of the following, is considered experimental, investigational or unproven:

- as part of the acute treatment (i.e., preoperative, immediately postoperative) of any fracture requiring open reduction and internal fixation (ORIF)
- fresh fractures (other than for the above listed indications)
- stress fracture (other than for the above listed indication of stress fracture nonunion)

ELECTRICAL BONE GROWTH STIMULATOR: NON-SPINAL (HCPCS code E0747, E0749)

A non-spinal electrical bone growth stimulator (non-invasive or invasive) is considered medically necessary for ANY of the following indications:

- Treatment of a fracture nonunion, when 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 joint fusion was performed.
- Nonunion of a stress fracture when ALL of the following criteria are met:
 - it is \geq three months from initial identification of the stress fracture
 - failure of a minimum of 90 days of conventional, nonsurgical management (e.g., rest, bracing)
 - radiograph imaging studies at least 90 days from the initial identification of the stress fracture demonstrates a fracture line that has not healed

A non-spinal electrical bone growth stimulator (non-invasive or invasive) for ANY other indication, including ANY of the following, is considered experimental, investigational or unproven:

- 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)
- stress fracture (other than for the above listed indication of stress fracture nonunion)

ELECTRICAL BONE GROWTH STIMULATOR: SPINAL (HCPCS Codes E0748, E0749)

An invasive or noninvasive spinal electrical bone growth stimulator as an adjunct to lumbar spinal fusion surgery is considered medically necessary for ANY of the following indications associated with an increased risk for fusion failure:

- prior spinal fusion at the same lumbar level (i.e., repeat spinal fusion)
- multi-level lumbar fusion (i.e., > 1 level)
- in the presence of any risk factor for nonhealing (e.g., smoking, diabetes, renal disease)

A noninvasive spinal electrical bone growth stimulator is considered medically necessary for treatment of a failed lumbar fusion when recent imaging confirms nonunion and it has been at least nine months since the lumbar fusion surgery.

ELECTRICAL SPINAL/NON-SPINAL: EXPERIMENTAL, INVESTIGATIONAL, UNPROVEN

The use of an electrical bone growth stimulator (spinal, non-spinal, invasive, non-invasive) for ANY other indication, including the following, is considered experimental, investigational or unproven:

- toe fracture
- sesamoid fracture
- avulsion fracture
- osteochondral lesion
- displaced fractures with malalignment
- synovial pseudoarthrosis
- the bone gap is either > 1 cm or $>$ one-half the diameter of the bone
- pars interarticularis defect (i.e., spondylolysis, spondylolisthesis)
- as an adjunct to cervical spinal fusion surgery
- stress fracture (other than for the above listed indication of stress fracture nonunion)

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 humerus, radius, ulna, femur, tibia and fibula. Other bones such as the clavicle,

metacarpals, and metatarsals are also considered long bones. 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.

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, 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).

In addition, depending on the type of bone, some bones are more prone to 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).

Healing time varies although 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.

Healing and nonunion of bones may be evaluated using 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. 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) is present when the nonunion is evident throughout the entire body of the bone.

In order for healing of bone to occur there needs to be adequate blood supply, stabilization and new tissue formation. Healing begins at the time of injury. The application of physical fields (magnetic, electrical, sonic) such as that from bone growth stimulators has been shown to be an effective treatment option to enhance bone growth and healing (AAOS, 2007). Selecting the type of device, the timing of application, and the duration of use depends on numerous factors. While there is no consensus regarding exact timing for application of devices such as the ultrasound or noninvasive electrical device, application of these devices should occur within a reasonable timeframe in order to enhance the normal healing process.

Bone growth stimulators are only indicated for use 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 (US) 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. 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 (Whittle, 2021). 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 has occurred.

According to the manufacturer the safety and effectiveness of ultrasound bone growth stimulation has not been established for 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 nonunion. Device labeling excludes nonunion 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 no established clinical definition in the peer-reviewed scientific literature to describe a fresh fracture. In general, "fresh" is defined as less than one week from the time of injury. While time to heal rate has been investigated by some authors to better define when a fracture is no longer considered fresh (Zura, et al., 2017), an accepted clinical definition of "fresh" fracture has yet to be established.

Published evidence also suggests 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 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). In another systematic review the authors noted an average healing rate of 87% among trials evaluating low intensity ultrasound for treatment of nonunion (Dijkman, et al., 2009). The evidence is not sufficient to support low-intensity pulsed ultrasound for the prevention of postmenopausal bone loss (Leung, et al., 2004).

A Hayes Medical Directory Technology report analyzed the evidence for low intensity pulsed ultrasound as an adjunct to conventional fracture care (Hayes, 2015). The evidence reviewed consisted of RCTs (n=20) and studies without controls (n=6). Sample size within the studies ranged from 16-101 (for RCTs) and 60 to 1317 for non-controlled studies; follow-up extended from one week to six years after completion of treatment. Hayes

concluded the available studies evaluating low-intensity pulsed US for bone growth stimulation is reasonably safe. The evidence supports the effectiveness of US therapy for treatment of nonunion of bones other than the skull or vertebrae in skeletally mature patients. Hayes further noted while US bone growth stimulation may be effective for many other indications, the studies of US therapy in these patient populations do not provide reliable evidence of benefit due to a small number of studies, inconsistent results, or other shortcomings. Updated reviews published by Hayes since the initial report indicate there has been no change to the evidence.

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 lumbar or lumbosacral 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 lumbar or lumbosacral spinal fusion were considered high risk for failed fusion.

Although indications vary among devices, the use of these devices for the treatment of fresh (acute) fractures has not been clearly demonstrated (Hanneman, et al., 2012; Adie, et al., 2011; Moucha, Einhorn, 2003) and is not mentioned in FDA labeling. 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 pseudoarthrosis 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.

Stress fractures are a type of fracture that results from repeated stress to a bone which is generally less than the stress required to fracture the bone in a single episode. This type of fracture occurs typically in individuals who are athletic. Evidence in the peer-reviewed scientific literature evaluating electrical bone growth stimulators as a method to stimulate healing is mixed when used for treatment of stress fractures (Beck, et al., 2008; Benazzo, et al., 1995). However, stress fractures often occur in the lower extremities and involve navicular bones, tibia, tarsals, and metatarsal bones which may have compromised healing due to poor bloody supply. Treatment is initially aimed at rest and/or orthotic bracing for immobilization; treatment for delayed union/nonunion may require surgical intervention. Use of a bone growth stimulator may be an effective modality for treatment of a nonunion similar to other nonunion fractures, precluding surgical intervention.

Safety and effectiveness of electrical bone growth stimulation has not been established in the presence of 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. In addition fixation devices made from magnetic materials may compromise the effects of electric bone growth stimulators (Orthofix Inc., 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 lumbar or lumbosacral spinal fusion. Evidence supporting noninvasive electrical bone growth stimulation for failed lumbar fusion is limited; one multicenter case series (n=100) supported clinical efficacy of PEMF when used as a salvage treatment in individuals who had not experienced complete radiographic fusion at \geq nine months following lumbar fusion (Simmons, et al., 2004).

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, and multiple supplements to initial approvals have been granted. FDA labeling and indications for specific devices vary. For example, the EBI Bone Healing System (Orthofix[®], Inc., Lewisville, TX) is indicated for the treatment of fracture nonunion, failed fusions, and congenital pseudoarthrosis of the appendicular skeletal system; Biomet[®] SpinalPak (Orthofix[®], Inc., Lewisville, TX) is indicated as an adjunct electrical treatment to primary lumbar spinal fusion surgery for one or two levels. In 2004 the FDA granted PMA approval for Cervical-Stim[®] Model 505L Cervical Fusion System (Orthofix[®], Inc., Lewisville, TX) as an adjunct to cervical fusion in subjects at high risk for non-fusion.

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 as a treatment for failed lumbar or lumbosacral fusions or fracture nonunion. Although limited, there is some evidence to support clinical efficacy of a noninvasive electrical bone growth stimulator when used as a salvage treatment for failed lumbar fusion.

For cervical fusion the evidence in the peer-reviewed published literature is limited. Foley et al. (2008) published the results of an industry-sponsored investigational device exemption (IDE) study of pulsed electromagnetic field (PEMF) stimulation (using Cervical-Stim[®] Model 505L Cervical Fusion System, Orthofix, Inc.) as an adjunct to anterior cervical discectomy and fusion (ACDF) (n= 323). The study groups in this prospective randomized controlled trial consisted of individuals who were smokers and/or were undergoing multilevel cervical fusion and were randomized to receive PEMF following ACDF (n=163) or to receive only ACDF (n=160). Follow-up occurred at one, two, three, six and 12 months. It was noted that at six months the PEMF group had a significantly higher rate of fusion compared to the control group (83.6% versus 68.6%, p=.0065), however at 12 months there was no significant difference (92.8% versus 86.7%, p=.1129). At six months loss to follow-up in the PEMF group was 25.1% (83 subjects) and 26.2% in the control group as a result of either voluntary withdrawal, violation of the study protocol, or radiographs deemed not evaluable. Loss to follow-up at 12 months was reported at 78/323 (24.1%) with no rationale. At both six and 12 months there were no differences in other outcome measures which included visual analogue pain scores, neck disability index scores, and SF-12 scores. No major adverse events were reported and the authors concluded use of the device was safe in their clinical setting. Limitations of the trial include high loss to follow-up and inclusion of only those at risk for poor healing (e.g., subjects who smoked or had multilevel fusions). Furthermore, the results of the clinical trial do not support a significant advantage for the improvement of net health outcomes (e.g., improved fusion rates, improved function) and additional studies are needed to support clinical efficacy and improved net health outcomes.

Coric et al. (2018) evaluated 12 month outcomes following PEMF treatment of subjects at increased risk for pseudoarthrosis after ACDF procedures. As part of the study two evaluations were conducted: a post hoc analysis of high risk subjects from the FDA IDE trial, (not statistically powered) (Foley, et al., 2008) and a retrospective, multicenter open label (OL) cohort study consisting of 274 subjects at risk for pseudoarthrosis. In the OL study fusion rates were compared between PEMF treated subjects (using Cervical-Stim, Orthofix, Inc.) and historical controls of the FDA IDE trial. Risk factors for pseudoarthrosis in the OL study included one or more of the following: age 65 years or greater, multilevel arthrodesis (up to 5 levels), prior failed fusion at any level, habitual use of nicotine at the time of surgery, was diabetic, and /or was osteoporotic. The primary endpoint was fusion at six and 12 months, confirmed by continuous bridging bone on plain films as assessed by the treating surgeon (who was not blinded). In the post hoc analysis group at both six and 12 months PEMF treatment significantly increased fusion rates for subjects with at least one risk factor of being elderly (at least age 50 or 65), a nicotine user, osteoporotic or diabetic as well as for subjects who had at least two-level fusion and at least one risk factor. Results of the OL study also demonstrated that at six and 12 months PEMF significantly increased fusion rates (p<0.05). The authors concluded results of the study suggest PEMF stimulation is an effective adjunct to achieve fusion in a select subgroup of individuals at high risk for pseudoarthrosis following ACDF. A limitation of the study noted by the authors include use of a historical control in the OL study for comparison.

Hayes evaluated noninvasive electrical bone growth stimulation as an adjunct to spinal fusion or foot and ankle arthrodesis for promotion of bone healing (Hayes, 2016; updated 2021). A total of eight RCTs were included in

the review; four evaluating lumbar/lumbosacral fusion, one evaluating cervical fusion, and three evaluating arthrodesis of the foot/ankle. Sample size ranged from 30 to 323 subjects with follow-up that ranged from 12 months to 2 years (spinal fusion) and 28 weeks to one year (foot/ankle arthrodesis). The evidence supported overall safety and that treatment was more effective than placebo or no device for outcomes associated with lumbar/lumbosacral fusion (three of four studies), cervical fusion (one study) and after foot and ankle arthrodesis (one study). In one of two clinical trials, use of an active noninvasive device versus placebo did not improve outcomes of osteochondral lesions of the talus, while in the other study, use of the device improved outcomes compared to no device use. Updated reviews published by Hayes since the initial report indicate there has been no change to the evidence.

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. There are currently no FDA approved semi-invasive devices. 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.

Invasive 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 lumbar or lumbosacral 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. Evidence evaluating the use of invasive electrical devices for cervical fusion is lacking therefore conclusions regarding efficacy cannot be made.

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 (Zimmer Biomet, Warsaw, Indiana). The OsteoGen™ and OsteoGen™-D are designed for the treatment of fracture nonunion, with the latter model indicated only for use in multiple nonunion 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 nonunion.

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 direct current electrical bone growth stimulators as an adjunct to spinal fusion for some individuals (i.e., younger than age 60) (Kaiser, et al. 2014). Overall, there is sufficient evidence in the peer reviewed literature to support clinical efficacy for the use of invasive bone growth stimulators as an adjunct to spinal fusion.

A Hayes Medical Directory Technology (Hayes, 2016b) report analyzed the evidence for invasive electrical bone growth stimulation for treatment of delayed fracture, fracture nonunion and for individuals undergoing arthrodesis. A total of 11 trials were included in the assessment, three RCTs, three comparative, and five uncontrolled case series. Sample populations ranged from 10-143 per study, with five of the trials limited in scope to lumbar arthrodesis, one to cervical arthrodesis, two to foot/ankle arthrodesis, and three to delayed or

nonunion fracture treatment. Follow-up evaluations ranged from six months to 10 years. Hayes concluded there is mixed, low-quality evidence evaluating effectiveness of invasive electrical stimulation used as an adjunct to lumbar spinal arthrodesis. According to the report some of the evidence is older and suggests that invasive electrical stimulation as an adjunct to lumbar spinal arthrodesis may offer benefit to patients at high risk for pseudoarthrosis. However, findings from the available RCTs were conflicting, with 1 older RCT suggesting improved fusion rates with use and 2 newer, better-quality RCTs suggesting no benefit. The evidence was of very low quality for all other indications. The authors concluded overall the technology appears generally safe; with no serious or severe complications being attributable to the device used. Updated reviews published by Hayes since the initial report indicate there has been no change to the evidence (Hayes, 2020).

Professional Societies/Organizations

The North American Spine Society (NASS) published coverage policy recommendations for electrical bone growth stimulation (NASS, 2016). According to this document, the current evidence is insufficient to support a coverage recommendation for the use of low intensity pulsed ultrasound or combined magnetic field technology for spinal use. Electrical stimulation for augmentation of spinal fusion is indicated for all regions of the spine in individuals at high risk for pseudoarthrosis with specific criteria (i.e., fusion of 3 or more vertebrae, revision spinal fusion, smokers who cannot stop smoking prior to fusion [e.g., trauma], and in the presence of comorbidities). Electrical stimulation is not indicated for a primary spinal fusion without risk factors, spinal fusion of two vertebral levels without risk factors, presence of malignancy, as an adjunct for primary bone healing of a spinal fracture, and as nonsurgical treatment of an established pseudoarthrosis.

Use Outside of the US: Recommendations regarding the use of the bone growth stimulation devices in countries outside the United States are available. For example, the National Institute for Health and Clinical Excellence (NICE) issued a procedural guidance for the Exogen ultrasound bone healing system for long bone fractures with non-union or delayed healing (NICE, 2013). According to the guidance based on a review of the available evidence and committee opinion NICE found the evidence sufficient to support efficacy and utility for the use of Exogen for the treatment of long bone fractures with non-union; the evidence did not support use of the device for treating fractures with delayed union. NICE also published a procedural guidance which supports the use of low intensity pulsed ultrasound to promote fracture healing (NICE, 2010). In addition, regulatory device approval was found for some of the bone growth stimulation devices in countries outside the US, including but not limited to Europe (e.g., CE mark certification for CervicalStim) and Canada.

Medicare Coverage Determinations

	Contractor	Policy Name/Number	Revision Effective Date
NCD	National	Osteogenic Stimulators (150.2),	4/27/2005
NCD	National		
LCD	CGS Administrators	Osteogenic Stimulators (L33796)	1/1/2020

Note: Please review the current Medicare Policy for the most up-to-date information.

Coding/Billing Information

- Note:** 1) This list of codes may not be all-inclusive.
 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

Ultrasound Bone Growth Stimulator

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

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

Electrical Bone Growth Stimulator: Non-spinal (Invasive, Non-invasive)

CPT®* Codes	Description
20974	Electrical stimulation to aid bone healing; noninvasive (nonoperative)
20975	Electrical stimulation to aid bone healing; invasive (operative)

HCPCS Codes	Description
E0747	Osteogenesis stimulator, electrical, non-invasive, other than spinal applications
E0749	Osteogenesis stimulator, electrical, surgically implanted

Electrical Bone Growth Stimulator: Spinal (Invasive, Non-invasive)

Considered medically necessary when used as an adjunct to lumbar spinal fusion surgery associated with an increased risk for fusion failure or for a failed lumbar fusion:

CPT®* Codes	Description
20974	Electrical stimulation to aid bone healing; noninvasive (nonoperative)
20975	Electrical stimulation to aid bone healing; invasive (operative)

HCPCS Codes	Description
E0748	Osteogenesis stimulator, electrical, non-invasive, spinal applications
E0749	Osteogenesis stimulator, electrical, surgically implanted

Considered Experimental/Investigational/Unproven when used as an adjunct to cervical spinal fusion surgery:

CPT®* Codes	Description
20974	Electrical stimulation to aid bone healing; noninvasive (nonoperative)
20975	Electrical stimulation to aid bone healing; invasive (operative)

HCPCS Codes	Description
E0748	Osteogenesis stimulator, electrical, non-invasive, spinal applications
E0749	Osteogenesis stimulator, electrical, surgically implanted

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