Medical Coverage Policy

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

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INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, 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 supersedes 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. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers

must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. 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. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

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

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.

<u>ULTRASOUND BONE GROWTH STIMULATOR (HCPCS code E0760)</u>

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 not medically necessary:

- 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 ≥ 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 not medically necessary:

- 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: NOT MEDICALLY NECESSARY

The use of an electrical bone growth stimulator (spinal, non-spinal, invasive, non-invasive) for ANY other indication, including the following, is considered not medically necessary:

- toe fracture
- sesamoid fracture
- avulsion fracture
- osteochondral lesion
- displaced fractures with malalignment
- synovial pseudoarthrosis
- the bone gap is either > 1cm 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)

Health Equity Considerations

Bone healing is multifactorial and dependent on factors such as general health and nutritional status, presence of infection, diminished blood flow to the fracture site, (e.g., smoking, malnutrition, diabetes mellitus, advanced age, alcoholism, peripheral vascular disease) and the use of some medications such as steroids. As such, some patients with an unmet health-related social need may be at a higher risk for non-healing of bone fractures.

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. Factors such as general health and nutritional status, presence of infection, diminished blood flow to the fracture site, (e.g., smoking, malnutrition, diabetes mellitus, advanced age, alcoholism, peripheral vascular disease) and the use of some medications such as steroids can all impact the healing process. Other characteristics such as extensive damage, misalignment, and soft tissue involvement, may also contribute to poor healing of bone (Sheen, Garla, 2024).

Furthermore, 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, 2014). 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 (Howe, et al, 2022).

Healing time varies although approximately ten percent of fractures result in nonunion or delayed union (Sheen, Garla, 2024). 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, calcaneus) 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, 2014). 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 device is intended to be used by the patient at home and is applied for 20–30 minutes daily until healing has occurred, although the exact mechanism for fracture healing is unclear it is thought that ultrasound causes biochemical changes at the cellular level to accelerate bone formation. Authors hypothesize that ultrasound increases blood flow to the capillaries, enhancing cellular interaction (Rubin, et al., 2001).

According to the manufacturer 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 (Bioventus, 2023).

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. Although several devices are currently available, 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 however 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). Ultrasound is considered a reasonable treatment for those individuals whose metabolic status may be compromised by disease or medication (Rubin, et al, 2001), and when used for treatment of stress fractures, such as those of the tibia shaft (Bederka, Amendola, 2009). Overall, the body of evidence is moderate to low quality, however the evidence does support efficacy for these uses (Busse, et al., 2009; Dijkman, et al., 2009; Washington State Health Care Authority, 2009; Agency for Healthcare Research and Quality [AHRQ], 2005). 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 however is not sufficient to support low intensity pulsed ultrasound for the prevention of postmenopausal bone loss (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 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 (Matityahu, Marmor, 2020; Hanneman, et al., 2012; Adie, et al., 2011) 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). Electrical bone growth stimulation is also 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 illustrates clinical outcomes are 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, 2024).

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 ≥ 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 pseduoarthrosis 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 pseduoarthrosis. 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 pseduoarthrosis following ACDF. A limitation of the study noted by the authors include use of a historical control in the OL study for comparison.

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. 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. 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 bone growth stimulators are indicated for nonunion of the tibia, femur and humerus and have also been proven 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 mellitus. 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, the OsteoGen™ and the SpF® Implantable Spine Fusion Stimulator (Zimmer Biomet, Warsaw, Indiana) are two such devices. 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 (Washington State Healthcare Authority, 2009; AHRQ, 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 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.

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 pseduoarthrosis 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 pseduoarthrosis.

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	Osteogenic Stimulators (150.2)	4/27/2005
LCD	CGS Administrators	Osteogenic Stimulators (L33796)	1/1/2024

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

Coding Information

Notes:
1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
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 Not Medically Necessary 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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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. Akhter S, Qureshi AR, Aleem I, El-Khechen HA, Khan S, Sikder O, Khan M, Bhandari M, Aleem I. Efficacy of Electrical Stimulation for Spinal Fusion: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. Sci Rep. 2020 Mar 12;10(1):4568.

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Revision Details

Type of Revision	Summary of Changes	Date
Annual review	No policy statement changes.	5/15/2024