Medical Coverage Policy

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Coverage Policy Number............ 0084

Bone Growth Stimulators: Electrical (Invasive), 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 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., nicotine dependence, diabetes, renal disease)
- Nonunion of fractures when ALL of the following criteria are met:
    - treatment is for nonunion of bones other than the skull (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)

<u>ELECTRICAL BONE GROWTH STIMULATOR: NON-SPINAL</u>

A non-spinal electrical bone growth stimulator (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 (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., nicotine dependence, diabetes, renal disease)
- stress fracture (other than for the above listed indication of stress fracture nonunion)

<u>ELECTRICAL NON-SPINAL: NOT MEDICALLY NECESSARY</u>

The use of an electrical bone growth stimulator (non-spinal, 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
- stress fracture (other than for the above listed indication of stress fracture nonunion)

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

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

Electrical Bone Growth Stimulator: Non-spinal (Invasive)

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

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., nicotine dependence, malnutrition, diabetes mellitus, advanced age, alcoholism, peripheral vascular disease) and the use of some medications such as steroids can all impact the healing process. Nicotine inhibits angiogenesis and forms weak calluses with an overall delay in the fracture healing process. Nicotine dependence can be in the form of smoking, using chew, or non-tobacco devices such as vaping or the use of electronic cigarettes and has been shown to decrease healing, and increase risk of postoperative complications such as increased risk of infection after a procedure, deep vein thrombosis, pulmonary embolism, and sepsis (DeShazo et al., 2024; Pescatore et al., 2024; Zaidi et al., 2024; Ashour et al., 2023). Other characteristics such as extensive damage, misalignment, and soft tissue involvement may also contribute to poor healing of bone (Sheen et al., 2023).

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, 2026). 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, 2025).

Healing time varies although approximately ten percent of fractures result in nonunion or delayed union (Sheen et al., 2023). 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], 2005). 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, 2026). 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, 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, 2025).

U.S. Food and Drug Administration (FDA): Ultrasound bone growth stimulators are regulated by the U.S. Food and Drug Administration (FDA) through the Premarket Approval (PMA) pathway and are classified as Class III medical devices. The FDA originally approved the technology through a PMA granted to Smith & Nephew, Inc. for the Sonic Accelerated Fracture Healing System (SAFHS®) Model 2A, with subsequent PMA supplements incorporating design and labeling changes. The currently marketed devices are collectively branded as Exogen® (e.g., models 2000, 3000, and 4000). Across devices, the cleared indications are consistent and generally include the treatment of fresh closed Colles' fractures, fresh closed or open tibial diaphyseal fractures, and established nonunion fractures, based on device labeling and supporting clinical evidence. FDA labeling consistently excludes treatment of nonunion involving the skull or vertebrae.

Device or Product	Identifier	Manufacturer
Exogen 4000+ Bone Healing System	P900009, S022	Bioventus, LLC
Exogen® 3000 SONIC Accelerated Fracture Healing System	P900009, S012	Bioventus, LLC
Exogen® 2000/Sonic Accelerated Fracture Healing System	P900009, S011	Bioventus, LLC
Sonic Accelerated Fracture Healing System (SAFHS®)	P900009	Bioventus, LLC

*FDA product codes: LOF, LPQ

Note: Coverage decisions are not based solely on FDA approval. Device or product names are provided for example purposes only. Their inclusion does not indicate endorsement or preference for any specific brand or model. This list is not intended to reflect all available products or technologies.

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 (Cook, et al., 1997; Kristiansen, et al., 1997; Heckman, et al., 1994). 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 and 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). 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 fractures.

Although indications vary among devices, the use of these devices for the treatment of fresh (acute) fractures has not been clearly demonstrated (Matityahu and Marmor, 2020; Hanneman, et al., 2012; Adie, et al., 2011) and is not mentioned in FDA labeling. 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.

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. Invasive bone growth stimulators are indicated for nonunion of the tibia, femur and humerus.

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.

U.S. Food and Drug Administration (FDA): There are many FDA approved invasive bone growth stimulator devices, the OsteoGen™ is one device. 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. 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).

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

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., nicotine dependence, 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.

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Revision Details

Type of Revision	Summary of Changes	Date
Annual review	• No clinical policy statement changes.	5/15/2026
Annual review	• No clinical policy statement changes. • Replaced the word “smoking” with “nicotine dependence” as one of the co-morbidities that delay wound healing	5/15/2025
Focused review	• Removed all spine related content. Spinal Growth Simulators are addressed in the Cigna/EviCore cobranded guidelines and therefore removed from this policy.	11/1/2024
Annual review	• No clinical policy statement changes.	5/15/2024