Introduction

An electrical bone growth stimulator can be used to help a broken bone heal in certain situations. The stimulators send electrical pulses or current through tissues, toward the bone. Electrical bone growth stimulators appear to encourage the growth of bone cells. Electrical bone growth stimulators are either noninvasive, invasive (implantable), or semi-invasive (semi-implantable).

- Noninvasive stimulators deliver current through small patches (electrodes) or coils placed near the broken bone.
- Invasive electrical stimulation use devices that are implanted in the body.
- Semi-invasive stimulators use needle-like electrodes placed through the skin.

This policy discusses when noninvasive electrical bone growth stimulators may be approved. Invasive and semi-invasive bone growth stimulators are considered unproven (investigational). More study is needed on these two types of stimulators to see if they are safe and effective.
**Note:** The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

## Policy Coverage Criteria

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Medical Necessity</th>
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| Noninvasive electrical bone growth stimulation | Noninvasive electrical bone growth stimulation may be considered medically necessary as treatment of fracture nonunions or congenital pseudoarthrosis in the appendicular skeleton (the appendicular skeleton includes the bones of the shoulder girdle, upper extremities, pelvis, and lower extremities). The diagnosis of fracture nonunion must meet ALL of the following criteria:  
  - At least 3 months have passed since the date of fracture  
  AND  
  - Serial radiographs have confirmed that no progressive signs of healing have occurred  
  AND  
  - The fracture gap is 1 cm or less  
  AND  
  - The fracture can be adequately immobilized  
  AND  
  - The patient is of an age likely to comply with nonweight bearing for fractures of the pelvis and lower extremities |

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Investigational</th>
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</table>
| Noninvasive electrical bone growth stimulation | Investigational applications of electrical bone growth stimulation include, but are not limited to:  
  - Delayed union  
  - Fresh fracture  
  - Stress fractures  
  - Immediate postsurgical treatment after appendicular skeletal surgery |
### Procedure

**Investigational**

- Arthrodesis
- Failed arthrodesis

**Implantable and semi-invasive electrical bone growth stimulators**

Implantable and semi-invasive electrical bone growth stimulators are considered investigational.

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### Documentation Requirements

The patient’s medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:

- Relevant history and physical supporting diagnoses of fracture nonunions or congenital pseudoarthrosis in the appendicular skeleton (the appendicular skeleton includes the bones of the shoulder girdle, upper extremities, pelvis, and lower extremities)

In addition, for diagnosis of fracture nonunion, **ALL of the following criteria must be met:**

- The fracture happened at least 3 months ago
- Serial radiographs confirm that no progressive signs of healing have occurred
- The width of the break is less than 1 centimeter (about 1/3 of an inch)
- Patient is able to limit physical movements
- Patient is of an age likely to comply with staying nonweight bearing during treatment for fractures of the pelvis and lower extremities

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### Coding

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<td>20974</td>
<td>Electrical stimulation to aid bone healing; noninvasive (non-operative)</td>
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<td>20975</td>
<td>Electrical stimulation to aid bone healing; invasive (operative)</td>
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<td><strong>HCPCS</strong></td>
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<td>E0747</td>
<td>Osteogenesis stimulator, electrical, noninvasive, other than spinal applications</td>
</tr>
<tr>
<td>E0749</td>
<td>Osteogenesis stimulator, electrical, surgically implanted</td>
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</table>
Definition of Terms

**Appendicular skeleton:** The appendicular skeleton includes the bones of the shoulder girdle, the upper extremities, the pelvis, and the lower extremities.

**Congenital pseudoarthrosis:** Congenital pseudoarthrosis of the tibia (CPT) is a rare condition that is usually seen shortly after birth and is rarely diagnosed after the age of two. It appears as a bowing of the tibial bone and could lead to a fracture if not found before the child begins to walk. Children with CPT may have poor healing ability and attempts to unite the small bone fragments can cause damage to the tibia and/or ankle joint. Congenital pseudoarthrosis of the tibia has been linked to Type 1 neurofibromatosis but the exact cause of CPT is unknown.²

**Delayed union:** Delayed union is defined as a decelerating healing process as determined by serial radiographs, together with a lack of clinical and radiologic evidence of union, bony continuity, or bone reaction at the fracture site for no less than 3 months from the injury or the most recent intervention. In contrast, fracture nonunion (described below) serial radiographs show no evidence of healing. When lumped together, delayed union and nonunion are sometimes referred to as “ununited fractures.”

**Fracture nonunion:** No consensus on the definition of fracture nonunions currently exists. One proposed definition is failure of progression of fracture healing for at least 3 consecutive months (and at least 6 months following the fracture) accompanied by clinical symptoms of delayed/nonunion such as pain, difficulty weight bearing (Bhandari et al, 2012).

The original U.S. Food and Drug Administration (FDA) labeling of fracture nonunions defined them as fractures not showing progressive healing after at least 9 months from the original injury. The labeling states: “A nonunion is considered to be established when a minimum of 9 months has elapsed since injury and the fracture site shows no visibly progressive signs of healing for minimum of 3 months.” This timeframe is not based on physiologic principles but was included as part of the research design for FDA approval as a means of ensuring homogeneous populations of patients, many of whom were serving as their own controls. Others have contended that 9 months represents an arbitrary cutoff point that does not reflect
the complicated variables present in fractures (ie, degree of soft tissue damage, alignment of the bone fragments, vascularity, quality of the underlying bone stock). Some fractures may show no signs of healing, based on serial radiographs as early as 3 months, while a fracture nonunion may not be diagnosed in others until well after 9 months. The current policy of requiring a 3-month timeframe for lack of progression of healing is consistent with the definition of nonunion as described in the clinical literature.

**Fresh fracture:** A fracture is most commonly defined as “fresh” for 7 days after its occurrence. Most fresh closed fractures heal without complications with the use of standard fracture care (ie, closed reduction and cast immobilization).

**Benefit Application**

State or federal mandates (eg, Federal Employee Program) may dictate that certain U.S. Food and Drug Administration‒approved devices, drugs, or biologics may not be considered investigational, and thus these devices may be assessed only on the basis of their medical necessity. Noninvasive electrical bone growth stimulation devices may be adjudicated according to the benefits for durable medical equipment.

**Evidence Review**

**Description**

In the appendicular skeleton, electrical stimulation with either implantable electrodes or noninvasive surface stimulators has been investigated to facilitate the healing of fresh fractures, stress fractures, delayed union, nonunion, congenital pseudoarthroses, and arthrodesis.

**Background**

**Delayed Fracture Healing**

Most bone fractures heal spontaneously over a few months postinjury. Approximately 5% to 10% of all fractures have delayed healing, resulting in continued morbidity and increased utilization of health care services.¹
There is no standard definition of a fracture nonunion. The Food and Drug Administration (FDA) labeling for one of the electrical stimulators included in this review defined nonunion as follows: "A nonunion is considered to be established when a minimum of 9 months has elapsed since injury and the fracture site shows no visibly progressive signs of healing for a minimum of 3 months." Others have contended that 9 months represents an arbitrary cutoff point that does not reflect the complicated variables present in fractures (ie, the degree of soft tissue damage, alignment of the bone fragments, vascularity, quality of the underlying bone stock). Other proposed definitions of nonunion involve 3 to 6 months from the original injury, or simply when serial radiographs fail to show any further healing. According to FDA labeling for a low-intensity pulsed ultrasound device, “a nonunion is considered to be established when the fracture site shows no visibly progressive signs of healing.” Factors contributing to a nonunion include: which bone is fractured, fracture site, the degree of bone loss, time since injury, the extent of soft tissue injury, and patient factors (eg, smoking, diabetes, systemic disease).

Delayed union is generally considered a failure to heal between 3 and 9 months postfracture, after which the fracture site would be considered a nonunion. Delayed union may also be defined as a decelerating bone healing process, as identified in serial radiographs. (In contrast, nonunion serial radiographs show no evidence of healing.) Together, delayed union and nonunion are sometimes referred to as "ununited fractures." To determine fracture healing status, it is important to include both radiographic and clinical criteria. Clinical criteria include the lack of ability to bear weight, fracture pain, and tenderness on palpation.

Fractures at certain locations (eg, scaphoid, proximal fifth metatarsal) are at greater risk of delayed union due to a tenuous blood supply. Systemic factors — including immunosuppression, cancer, and tobacco use — may also predispose patients to fracture nonunion, along with certain medications (eg, nonsteroidal anti-inflammatory drugs, fluoroquinolones).

**Treatment**

Individuals with recognized delayed fracture unions might begin by reducing the risk factors for delayed unions or nonunions but may progress to surgical repair if it persists.

**Electrical and Electromagnetic Bone Growth Stimulators**

Different applications of electrical and electromagnetic fields have been used to promote healing of delayed and nonunion fractures: invasive, noninvasive, and semi-invasive.
• **Invasive:** Invasive stimulation involves the surgical implantation of a cathode at the fracture to produce direct-current electrical stimulation. Invasive devices require surgical implantation of a current generator in an intramuscular or subcutaneous space, while an electrode is implanted within the fragments of bone graft at the fusion site. The implantable device typically remains functional for 6 to 9 months after implantation, and, although the current generator is removed in a second surgical procedure when stimulation is completed, the electrode may or may not be removed. Implantable electrodes provide constant stimulation at the nonunion or fracture site but carry increased risks associated with implantable leads.

• **Noninvasive:** Noninvasive electrical bone growth stimulators generate a weak electrical current within the target site using pulsed electromagnetic fields, capacitive coupling, or combined magnetic fields. In capacitive coupling, small skin pads/electrodes are placed on either side of the fusion site and worn for 24-hours per day until healing occurs, or up to 9 months. In contrast, pulsed electromagnetic fields are delivered via treatment coils that are placed on the skin over the fracture and are worn for 6-hours to 8-hours per day for 3 to 6 months. Combined magnetic fields deliver a time-varying magnetic field by superimposing the time-varying magnetic field onto an additional static magnetic field. This device involves a 30-minute treatment period each day for 9 months. Patient compliance may be an issue with externally worn devices.

• **Semi-Invasive:** Semi-invasive (semi-implantable) stimulators use percutaneous electrodes and an external power supply, obviating the need for a surgical procedure to remove the generator when treatment is finished.

**Summary of Evidence**

**Noninvasive Electrical Bone Growth Stimulation**

For individuals who have fracture nonunion who receive noninvasive electrical bone growth stimulation, the evidence includes randomized controlled trials (RCTs) and systematic reviews of RCTs. Relevant outcomes are symptoms, change in disease status, and functional outcomes. The U.S. Food and Drug Administration has approved noninvasive electrical bone growth stimulation for fracture nonunions or congenital pseudoarthroses in the appendicular skeleton, based largely on studies with patients serving as their own controls. There is also evidence from 2 small sham-controlled randomized trials that noninvasive electrical stimulators improve fracture healing for patients with fracture nonunion. There are few nonsurgical options in this population, and the pre/post studies of patients with nonhealing fractures support the efficacy
of the treatment. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals with delayed fracture union, fresh or stress fracture(s), or who have had surgery of the appendicular skeleton who receive noninvasive electrical bone growth stimulation, the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are symptoms, change in disease status, and functional outcomes. A meta-analysis of 5 RCTs found no statistically significant benefit of electrical bone growth stimulation for fresh fractures. RCTs on delayed union of the other types of fractures were limited by small sample sizes and did not show significant differences in outcomes between study groups. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Invasive Electrical Bone Growth Stimulation**

For individuals with fracture or pseudoarthroses or who have had surgery of the appendicular skeleton who receive implantable and semi-invasive bone growth stimulation, the evidence includes a small number of case series. Relevant outcomes are symptoms, change in disease status, and functional outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Ongoing and Unpublished Clinical Trials**

A search of ClinicalTrials.gov in March 2018 did not identify any ongoing or unpublished trials that would likely influence this review.

**Clinical Input Received from Physician Specialty Societies and Academic Medical Centers**

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 5 academic medical centers while this policy was under review in 2012. Input supported the use of noninvasive electrical bone growth
stimulation for the treatment of fracture nonunions or congenital pseudoarthroses of the appendicular skeleton. Input concurred that noninvasive electrical bone growth stimulation is investigational for the treatment of fresh fractures and immediate postsurgical treatment after appendicular skeletal surgery. Most reviewers considered the use of noninvasive electrical bone growth stimulation to be investigational for the treatment of delayed union, arthrodesis, or failed arthrodesis.

**Medicare National Coverage**

Noninvasive stimulators are covered for the following indications:

- “Nonunion of long bone fractures;
- “Failed fusion, where a minimum of 9 months has elapsed since the last surgery;
- Congenital pseudarthroses…”

Invasive stimulators are covered for:

- “Nonunion of long bone fractures.”

“Effective April 1, 2000, nonunion of long bone fractures is considered to exist only when serial radiographs have confirmed that fracture healing has ceased for 3 or more months prior to starting treatment with the electrical osteogenic stimulator. Serial radiographs must include a minimum of 2 sets of radiographs, each including multiple views of the fracture site, separated by a minimum of 90 days.”

**Regulatory Status**

In 1984, the noninvasive OrthoPak® Bone Growth Stimulator (BioElectron, now Zimmer Biomet) was approved by the FDA through the premarket approval process for treatment of fracture nonunion. Pulsed electromagnetic field systems with FDA premarket approval (all noninvasive devices) include Physio-Stim® (Orthofix), first approved in 1986, and OrthoLogic® 1000, approved in 1997, both indicated for treatment of established nonunion secondary to trauma, excluding vertebrae and all flat bones, in which the width of the nonunion defect is less than one-half the width of the bone to be treated; and the EBI Bone Healing System® (Electrobiology, now Zimmer Biomet), which was first approved in 1979 and indicated for nonunions, failed fusions, and congenital pseudoarthroses. No distinction was made between
long and short bones. The FDA has approved labeling changes for electrical bone growth stimulators that remove any timeframe for the diagnosis.

No semi-invasive electrical bone growth stimulator devices with FDA approval or clearance were identified.

FDA product code LOF.

References


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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
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