Electrical Bone Growth Stimulation of the Appendicular Skeleton

Introduction

An electrical bone growth stimulator can be used to help a broken bone heal in some cases. These 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 break.
- 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.

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 staying nonweight bearing during treatment 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 | Applications of noninvasive electrical bone growth stimulation that are considered investigational include, but are not limited to:  
  - Arthrodesis  
  - Delayed union  
  - Failed arthrodesis  
  - Immediate postsurgical treatment after appendicular skeletal |
**Procedure**

Investigational surgery
- In the absence of the criteria listed above
- Stress fractures
- Treatment of fresh fractures

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

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

**Coding**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>CPT</td>
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<tr>
<td>20974</td>
<td>Electrical stimulation to aid bone healing; noninvasive (non-operative)</td>
</tr>
<tr>
<td>20975</td>
<td>Electrical stimulation to aid bone healing; invasive (operative)</td>
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<tr>
<td>HCPCS</td>
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</tr>
<tr>
<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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</tbody>
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**Related Information**

**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 pseudarthrosis 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 decline in the healing process as determined by serial x-rays, together with a lack of clinical and radiologic evidence. Documentation must show delayed 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, nonunion serial x-rays (described below) show no evidence of healing. When lumped together, delayed union and nonunion are sometimes referred to as “ununited fractures.”

**Fresh fracture:** A fracture is most commonly defined as “fresh” for 7 days after the fracture occurs. Most fresh closed fractures heal without complications with the use of standard fracture care such as closed reduction and immobilization using a cast.

**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)

**Benefit Application**

State or federal mandates 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**

Electrical stimulation with noninvasive surface stimulators has been shown to improve the healing of nonunions of broken bones (fractures) and congenital pseudoarthrosis in the
appendicular skeleton. The evidence for other indications using either implantable electrodes or noninvasive surface stimulators fails to show an effect on health outcomes.

Background

Delayed Fracture Healing

Most bone fractures heal spontaneously over a few months after injury. 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.

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).

Electrical and Electromagnetic Bone Growth Stimulators

Electrical and electromagnetic fields can be generated and applied to bones through the following methods:

- Surgical implantation of a cathode at the fracture site that produces 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 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 to 8 hours per day for 3 to 6 months. Combined magnetic fields deliver a time-varying magnetic field superimposed 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-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

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.

Noninvasive Electrical Bone Growth Stimulation

The evidence for noninvasive electrical bone growth stimulators in individuals who have fracture nonunion includes randomized controlled trials (RCTs) and systematic reviews of clinical trials. Relevant outcomes are symptoms, change in disease status, and functional outcomes. The U.S. Food and Drug Administration (FDA) has approved noninvasive electrical bone growth stimulators for the indications of 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. However, 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.
The evidence for noninvasive bone growth stimulation in individuals who have delayed union, fresh or stress fractures, or who have had surgery of the appendicular skeleton 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**

The evidence for implantable and semi-invasive bone growth stimulation in individuals who have any type of fracture, pseudoarthroses, or who have had surgery of the appendicular skeleton 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 2017 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 provide appropriate reviewers who collaborate with and make recommendations during this process, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.
2012 Input

In response to requests, input was received from 5 academic medical centers while this policy was under review in 2012. The input supported use of noninvasive electrical bone growth stimulation for the treatment of fracture nonunions or congenital pseudoarthroses of the appendicular skeleton. Input agreed that noninvasive electrical bone growth stimulation is investigational for immediate postsurgical treatment after appendicular skeletal surgery and treatment of fresh fractures. Most reviewers considered the use of noninvasive electrical bone growth stimulation to be investigational for the treatment of delayed union, for arthrodesis, or for the treatment of 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 for services performed on or after April 1, 2000, nonunion of long bone fractures, for both noninvasive and invasive devices, 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 U.S. Food and Drug Administration (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®** from Orthofix Inc. (1986)
- **OrthoLogic® 1000** (1997)

Both devices are 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.

The EBI Bone Healing System® from Electrobiology Inc. was first approved in 1979 and is 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.

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**References**


**History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>04/14/15</td>
<td>New Policy. Policy replaces 7.01.529. Policy developed with literature review through November 4, 2014.</td>
</tr>
<tr>
<td>07/01/16</td>
<td>Annual Review, approved June 14, 2016. Policy statements rewritten for usability, intent unchanged. Policy updated with literature review through March, 2016; one reference added. Added definition of congenital pseudoarthrosis. Policy statements intent is unchanged.</td>
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</table>

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Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357

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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room S09F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at

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Call 800-722-1471 (TTY: 800-842-5357).

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Kazakh (Khmer):
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