

# Protocol

## Electrical Bone Growth Stimulation of the Appendicular Skeleton

(70107)

<b>Medical Benefit</b>		<b>Effective Date:</b> 04/01/14	<b>Next Review Date:</b> 01/18
<b>Preauthorization</b>	Yes	<b>Review Dates:</b> 09/07, 09/08, 09/09, 05/10, 03/11, 01/12, 01/13, 01/14, 01/15, 01/16, 01/17	

### ***Preauthorization is required.***

*The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Populations	Interventions	Comparators	Outcomes
Individuals: • With fracture nonunion	Interventions of interest are: • Noninvasive electrical bone growth stimulation	Comparators of interest are: • No treatment • Surgery	Relevant outcomes include: • Symptoms • Change in disease status • Functional outcomes
Individuals: • With delayed union, fresh or stress fractures, or who have had surgery of the appendicular skeleton	Interventions of interest are: • Noninvasive electrical bone growth stimulation	Comparators of interest are: • No treatment • Surgery	Relevant outcomes include: • Symptoms • Change in disease status • Functional outcomes
Individuals: • With any type of fracture, pseudoarthroses, or who have had surgery of the appendicular skeleton	Interventions of interest are: • Implantable and semi-invasive electrical bone growth stimulation	Comparators of interest are: • No treatment • Surgery	Relevant outcomes include: • Symptoms • Change in disease status • Functional outcomes

### **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.

### **Summary of Evidence**

The evidence for noninvasive electrical bone growth stimulation 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. There is evidence from these studies that noninvasive electrical stimulators improve fracture healing for patients with fracture nonunion. However, the evidence is not from high-quality RCTs, and the systematic reviews provide only qualified support for this conclusion. The U.S. Food and Drug Administration (FDA) has approved noninvasive electrical bone growth stimulation for the indications of fracture nonunions and congenital pseudoarthroses in the appendicular skele-

ton, and it is acknowledged that there are limited other options in this population. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

The evidence for noninvasive electrical bone growth stimulation in individuals who have delayed union, fresh or stress fractures, or who have had surgery of the appendicular skeleton includes RCTs. Relevant outcomes are symptoms, change in disease status, and functional outcomes. Two RCTs found no benefit of electrical bone growth stimulation for fresh fractures. RCTs on delayed union of the other types of fractures were limited by small sample size and did not show a significant difference between study groups. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for implantable and semi-invasive electrical 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.

## Policy

Noninvasive electrical bone growth stimulation may be considered **medically necessary** as treatment of fracture nonunions or congenital pseudoarthroses 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 three months have passed since the date of fracture;
- serial radiographs have confirmed that no progressive signs of healing have occurred;
- the fracture gap is one cm or less;
- the patient can be adequately immobilized; and
- the patient is of an age likely to comply with non-weight bearing for fractures of the pelvis and lower extremities.

Noninvasive electrical bone growth stimulation for treatment of fracture nonunions or congenital pseudoarthroses in the appendicular skeleton is considered **investigational** if all of the above criteria are not met.

**Investigational** applications of electrical bone growth stimulation include, but are not limited to, delayed union, fresh fracture, immediate postsurgical treatment after appendicular skeletal surgery, stress fractures, arthrodesis or failed arthrodesis.

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

## Policy Guidelines

### *Nonunion*

No consensus on the definition of nonunion currently exists. One proposed definition is failure of progression of fracture-healing for at least three consecutive months (and at least six months following the fracture) accompanied by clinical symptoms of delayed union or nonunion (pain, difficulty weight bearing) (Bhandari, 2012).

The original FDA labeling of fracture nonunions defined them as fractures that had not shown progressive healing after at least nine months from the original injury. The labeling states: "A nonunion is considered to be established when a minimum of nine months has elapsed since injury and the fracture site shows no visibly progressive signs of healing for minimum of three months." This timeframe is not based on physiologic prin-

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 nine months represents an arbitrary cutoff point that does not reflect the complicated variables that are present in fractures (i.e., degree of soft tissue damage, alignment of the bone fragments, vascularity, and quality of the underlying bone stock). Some fractures may show no signs of healing, based on serial radiographs as early as three months, while a fracture nonunion may not be diagnosed in others until well after nine months. The current policy of requiring a three month timeframe for lack of progression of healing is consistent with the definition of nonunion as described in the clinical literature.

#### *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 three months from the index injury or the most recent intervention. In contrast, nonunion serial radiographs (described above) show no evidence of healing. When lumped together, delayed union and nonunion are sometimes referred to as “united fractures.”

#### *Fresh Fracture*

A fracture is most commonly defined as “fresh” for seven days after the fracture occurs. Most fresh closed fractures heal without complications with the use of standard fracture care, i.e., closed reduction and cast immobilization).

### **Medicare Advantage**

For Medicare Advantage the noninvasive stimulator device is **medically necessary** for the following indications:

- Nonunion of long bone fractures; and
- Congenital pseudarthroses.

An implantable bone growth stimulator is **medically necessary** for:

- Nonunion of long bone fractures.

It is **not medically necessary** to treat nonunion fractures of the skull, vertebrae and those that are tumor-related with electrical bone growth stimulators.

### **Medicare Advantage Policy Guidelines**

Nonunion of long bone fractures is considered to exist only after six or more months have elapsed without healing of the fracture and when serial radiographs have confirmed that fracture healing has ceased for three or more months prior to starting treatment with the electrical osteogenic stimulator. Serial radiographs must include a minimum of two sets of radiographs, each including multiple views of the fracture site, separated by a minimum of 90 days.

### **Background**

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

- Surgical implantation of a cathode at the fracture site with the production of 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 six to nine 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 nine months. In contrast, pulsed electromagnetic fields are delivered via treatment coils that are placed over the skin and are worn for six to eight hours per day for three to six 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 per day for nine 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.

### Regulatory Status

In 1984, the noninvasive OrthoPak® Bone Growth Stimulator (BioElectron) 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® (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 Inc.), which was first approved in 1979 and indicated for nonunions, failed fusions, and congenital pseudoarthroses. No distinction was made between long and short bones. 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.

### Related Protocols

Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures

Ultrasound Accelerated Fracture Healing Device

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Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

## References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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