

Protocol

Electrical Bone Growth Stimulation of the Appendicular Skeleton

(70107)

Medical Benefit		Effective Date: 04/01/14	Next Review Date: 01/20
Preauthorization	Yes	Review Dates: 09/07, 09/08, 09/09, 05/10, 03/11, 01/12, 01/13, 01/14, 01/15, 01/16, 01/17, 01/18, 01/19	

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: • Conservative therapy • Surgery	Relevant outcomes include: • Symptoms • Change in disease status • Functional outcomes
Individuals: • With delayed union, fresh fracture(s) or stress fracture(s)	Interventions of interest are: • Noninvasive electrical bone growth stimulation	Comparators of interest are: • Conservative therapy • Surgery	Relevant outcomes include: • Symptoms • Change in disease status • Functional outcomes
Individuals: • Who have had surgery of the appendicular skeleton	Interventions of interest are: • Noninvasive electrical bone growth stimulation	Comparators of interest are: • Standard postsurgical management	Relevant outcomes include: • Symptoms • Change in disease status • Functional outcomes
Individuals: • With fracture or with pseudoarthroses	Interventions of interest are: • Implantable and semi-invasive electrical bone growth stimulation	Comparators of interest are: • Conservative therapy • Surgery	Relevant outcomes include: • Symptoms • Change in disease status • Functional outcomes
Individuals: • Who have had surgery of the appendicular skeleton	Interventions of interest are: • Implantable and semi-invasive electrical bone growth stimulation	Comparators of interest are: • Standard postsurgical therapy	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

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 (FDA) has approved noninvasive electrical bone growth stimulation for fracture nonunions and congenital pseudoarthroses in the appendicular skeleton, based largely on studies with patients serving as their controls. There is also evidence from two 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 that the technology results in a meaningful improvement in the net health outcome.

For individuals who have 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 five RCTs found no statistically significant benefit of electrical bone growth stimulation for fresh fractures. RCTs on the 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 who have fracture, pseudoarthroses, or who have had surgery of the appendicular skeleton who receive implantable and semi-invasive electrical 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.

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, stress fractures, immediate postsurgical treatment after appendicular skeletal surgery, arthrodesis or failed arthrodesis.

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

POLICY GUIDELINES

FRACTURE 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 for at least six months following the fracture) accompanied by clinical symptoms of delayed union or nonunion (pain, difficulty bearing weight) (Bhandari et al, 2012).

The original FDA labeling of fracture nonunions defined them as fractures not showing 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 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 nine months represents an arbitrary cutoff point that does not reflect the complicated variables present in fractures (i.e., 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 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 its occurrence. 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

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.² The FDA labeling for one of the electrical stimulators included in this protocol 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 nine months represents an arbitrary cutoff point that does not reflect the complicated variables present in fractures (i.e., the degree of soft tissue damage, alignment of the bone fragments, vascularity, quality of the underlying bone stock). Other proposed definitions of nonunion involve three to six 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 (e.g., smoking, diabetes, systemic disease).¹

Delayed union is generally considered a failure to heal between three and nine 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 (e.g., 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 (e.g., 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 stimulation involves the surgical implantation of a cathode at the fracture site 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 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 a day until healing occurs or up to nine months. In contrast, pulsed electromagnetic fields are delivered via treatment coils placed over the skin and worn for six to eight hours a 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, 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. 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.

RELATED PROTOCOLS

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

Ultrasound Accelerated Fracture Healing Device

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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