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*The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is required.** 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.*

Description

In the appendicular skeleton, electrical stimulation (with either implantable electrodes or noninvasive surface stimulators) has been investigated for the treatment of delayed union, nonunion, and fresh fractures.

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 (DC) 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.

In the appendicular skeleton, electrical stimulation has been used primarily to treat tibial fractures, and thus this technique has often been thought of as a treatment of the long bones. According to orthopedic anatomy, the skeleton consists of long bones, short bones, flat bones, and irregular bones. Long bones act as levers to facilitate motion, while short bones function to dissipate concussive forces. Short bones include those composing the carpus and tarsus. Flat bones, such as the scapula or pelvis, provide a broad surface area for attachment of muscles. Despite their anatomic classification, all bones are composed of a combination of cortical and trabecular (also called cancellous) bone. Each bone, depending on its physiologic function, has a different proportion of cancellous to trabecular bone. At a cellular level, however, both bone types are composed of lamellar bone and cannot be distinguished microscopically.

Nonunion

The definition of a fracture nonunion has remained controversial. The original U.S. Food and Drug Administration (FDA) labeling defined nonunion as follows: "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." Others have contended that nine months represents an arbitrary cut-off 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. Other proposed definitions of nonunion involve three to six months' time from original healing, or simply when serial x-rays fail to show any further healing.

Delayed Union

Delayed union refers to a decelerating bone healing process, as identified in serial x-rays. (In contrast, nonunion serial x-rays show no evidence of healing.) When lumped together, delayed union and nonunion are sometimes referred to as "united fractures."

Regulatory Status

The noninvasive OrthoPak® Bone Growth Stimulator (BioElectron) received U.S. Food and Drug Administration (FDA) premarket approval in 1984 for treatment of fracture nonunion. Pulsed electromagnetic field systems with FDA premarket approval (all noninvasive devices) include Physio-Stim® from Orthofix Inc., 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® from Electrobiolog, 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. 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.

Related Protocols

Ultrasound Accelerated Fracture Healing Device

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

Bone Morphogenetic Protein

Policy (Formerly Corporate Medical Guideline)

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 1 cm or less;
- the patient can be adequately immobilized; and
- 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, immediate post-surgical treatment after appendicular skeletal surgery, stress fractures, or for the treatment of fresh fractures, delayed union, arthrodesis or failed arthrodesis.

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

Policy Guideline

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.

Delayed Union

Delayed union is defined as a decelerating healing process as determined by serial x-rays, 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.

Nonunion

There is not a consensus for the definition of nonunions. 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/nonunion (pain, difficulty weight bearing). (1)

The original FDA labeling of fracture nonunions defined nonunions as fractures that had not shown progressive healing after at least nine months from the original injury. 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. 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.

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.

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.

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

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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