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.

RELATED PROTOCOLS

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

Low Intensity Pulsed Ultrasound Fracture Healing Device

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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 pseudarthrosis, 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 pseudarthrosis in the appendicular skeleton, based largely on studies with patients serving as their 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 that the technology results in an improvement in the net health outcome.

For individuals who have delayed fracture union 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. RCTs on the delayed union 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 that the technology results in an improvement in the net health outcome.

For individuals who have fresh fracture(s) 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. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have stress fracture(s) who receive noninvasive electrical bone growth stimulation, the evidence includes an RCT. Relevant outcomes are symptoms, change in disease status, and functional outcomes. This well-conducted RCT found that, although an increase in the hours of use per day was associated with a reduction in the time to healing, there was no difference in the rate of healing between treatment and placebo. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have had surgery of the appendicular skeleton who receive noninvasive electrical bone growth stimulation, the evidence includes 2 small RCTs. Relevant outcomes are symptoms, change in disease status, and functional outcomes. Although the results of 1 trial suggest benefits to the bone stimulation in decreased time to union, clinical outcomes were not assessed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

**IMPLANTABLE AND SEMI-INVASIVE BONE GROWTH STIMULATION**

For individuals who have fracture, pseudarthrosis, 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 that the technology results in an improvement in the net health outcome.

**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 non-union 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 three 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 “ununited 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
- Failed fusion, where a minimum of nine months has elapsed since the last surgery
- 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
TREATMENT OF DELAYED AND NONUNION FRACTURES
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 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 a day until healing occurs or up to 9 months. In contrast, pulsed electromagnetic fields are delivered via treatment coils placed over the
skin and worn for 6 to 8 hours a 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 per 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.

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 the FDA premarket approval (all noninvasive devices) include Physio-Stim® (Orthofix), first approved in 1986, and OrthoLogic® 1000, approved in 1997, both indicated for the 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 pseudarthrosis. No distinction was made between long and short bones. The FDA has approved labeling changes for electrical bone growth stimulators that remove any time frame for the diagnosis. As of September 2020, under consideration is the reclassification of noninvasive electrical bone growth stimulators from Class III to the lower-risk Class II category.¹

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

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


29. Noridian Healthcare Solutions, LLC, (Jurisdiction - New York - Entire State, Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont, District of Columbia, Delaware, Maryland, New Jersey, Pennsylvania, California - Entire State, American Samoa, Guam, Hawaii, Northern Mariana Islands, Nevada), Local Coverage Determination (LCD): Osteogenesis STIMULATORS (L33796), Revision Effective Date for services performed on or after 01/01/2020.