BlueCross BlueShield Federal Employee Program.

# FEP Medical Policy Manual

## FEP 7.01.07 Electrical Bone Growth Stimulation of the Appendicular Skeleton

### Effective Policy Date: July 1, 2023

### Original Policy Date: June 2012

### Related Policies:

1.01.05 - Low Intensity Pulsed Ultrasound Fracture Healing Device
7.01.85 - Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures

## Electrical Bone Growth Stimulation of the Appendicular Skeleton

### 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.

## OBJECTIVE

The objective of this evidence review is to determine whether electrical bone growth stimulation of the appendicular skeleton improves the net health outcome in individuals with fractures or who have had bone surgery.

# POLICY STATEMENT

Noninvasive electrical bone growth stimulation may be considered **medically necessary** for the treatment of fracture nonunions or congenital pseudarthrosis 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;
- serial radiographs have confirmed that no progressive signs of healing have occurred;
- the fracture gap is 1 cm or less;
- the individual can be adequately immobilized; and
- the individual is of an age likely to comply with nonweight bearing for fractures of the pelvis and lower extremities.

**Not medically necessary** 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 fracture nonunion currently exists. One proposed definition is failure of progression of fracture healing for at least 3 consecutive months (and for at least 6 months following the fracture), accompanied by clinical symptoms of delayed union or nonunion (pain, difficulty bearing weight) (Bhandari et al, 2012).

The original U.S. Food and Drug Administration (FDA) labeling of fracture nonunions defined them as fractures not showing progressive healing after at least 9 months from the original injury. The labeling states: "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 minimum of 3 months.” This time frame 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 9 months represents an arbitrary cutoff point that does not reflect the complicated variables present in fractures (ie, 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 3 months, while a fracture nonunion may not be diagnosed in others until well after 9 months. The current policy of requiring a 3-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 3 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 7 days after its occurrence. Most fresh closed fractures heal without complications with the use of standard fracture care (ie, closed reduction, cast immobilization).

# BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

# FDA 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.

# RATIONALE

## 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.

# SUPPLEMENTAL INFORMATION

## Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

No guidelines or statements were identified.

## U.S. Preventive Services Task Force Recommendations

Not applicable.

## Medicare National Coverage

Noninvasive stimulators are covered by Medicare for the following indications[28,]:

- "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 April 1, 2000, nonunion of long bone fractures 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.”

## REFERENCES


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## POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

| Date | Action | Description |
|---|---|---|
| June 2012 | New policy | |
| September 2013 | Replace policy | Clinical input reviewed; references 1 and 16 added. Policy statements unchanged, policy summary revised with no change to intent. Policy guidelines added for consistency with policy Number 1.01.05. |
| March 2014 | Replace policy | Policy updated with literature review; references 10, 18, & 19 added; delayed union added to medically necessary statement, stress fractures added to not medically necessary statement; compliance with non-weight bearing clarified. |
| March 2015 | Replace policy | Policy updated with literature review; reference 18 added; policy statement unchanged |
| June 2017 | Replace policy | Policy updated with literature review through February 23, 2017; references 1-2, 8, 12, 18-19, and 21-22 added. Policy statements unchanged. |
| June 2018 | Replace policy | Policy updated with literature review through February 5, 2018; no references added. Policy statements unchanged except "not medically necessary, corrected to "investigational, for the statement: Implantable and semi-invasive electrical bone growth stimulators are considered investigational due to no devices are FDA approved. |
| June 2019 | Replace policy | Policy updated with literature review through February 5, 2019; no references added. Policy statements unchanged. |
| June 2020 | Replace policy | Policy updated with literature review through February 11, 2020; no references added. Pseudarthrosis added to the policy; statements otherwise unchanged. |
| June 2021 | Replace policy | Policy updated with literature review through January 11, 2021; 1 reference added; Policy statements unchanged. |
| June 2022 | Replace policy | Policy updated with literature review through January 17, 2022; no references added; Policy statements unchanged. |
| June 2023 | Replace policy | Policy updated with literature review through January 13, 2023; no references added. Minor editorial refinements to policy statements; intent unchanged. |