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MEDICAL POLICY – 7.01.07

Electrical Bone Growth Stimulation of the Appendicular Skeleton

BCBSA Ref. Policy:	7.01.07
Effective Date:	July 1, 2024
Last Revised:	June 10, 2024
Replaces:	7.01.529

RELATED MEDICAL POLICIES:

1.01.05	Low Intensity Pulsed Ultrasound Fracture Healing Device
1.01.507	Electrical Stimulation Devices
7.01.85	Electrical Bone Growth Stimulation of the Spine

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RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

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Introduction

An electrical bone growth stimulator can be used to help a broken bone heal in certain situations. The stimulators send electrical pulses or current through tissues, toward the bone. Electrical bone growth stimulators appear to encourage the growth of bone cells. Electrical bone growth stimulators are either noninvasive, invasive (implantable), or semi-invasive (semi-implantable).

- Noninvasive stimulators deliver current through small patches (electrodes), or coils placed near the broken bone.
- Invasive electrical stimulation use devices that are implanted in the body.
- Semi-invasive stimulators use needle-like electrodes placed through the skin.

This policy discusses when noninvasive electrical bone growth stimulators may be approved. Invasive and semi-invasive bone growth stimulators are considered unproven (investigational). More study is needed on these two types of stimulators to see if they are safe and effective.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for

providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Procedure	Medical Necessity
Noninvasive electrical bone growth stimulation	**Noninvasive electrical bone growth stimulation may be considered medically necessary for the treatment of fracture nonunions or congenital pseudoarthrosis 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 **AND** • Serial radiographs have confirmed that no progressive signs of healing have occurred **AND** • The fracture gap is 1 cm or less **AND** • 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

Procedure	Investigational
Noninvasive electrical bone growth stimulation	**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 • Failed arthrodesis

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

Documentation Requirements

The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:

- Relevant history and physical supporting diagnoses of fracture nonunions or congenital pseudoarthrosis in the appendicular skeleton (the appendicular skeleton includes the bones of the shoulder girdle, upper extremities, pelvis, and lower extremities)

In addition, for diagnosis of diagnosis of fracture nonunion, ALL of the following criteria must be met:

- The fracture happened at least 3 months ago
- Serial radiographs confirm that no progressive signs of healing have occurred
- The width of the break is less than 1 centimeter (about 1/3 of an inch)
- Individual is able to limit physical movements
- Individual is of an age likely to comply with staying nonweight bearing during treatment for fractures of the pelvis and lower extremities

Coding

Code	Description
CPT	
20974	Electrical stimulation to aid bone healing; noninvasive (non-operative)
20975	Electrical stimulation to aid bone healing; invasive (operative)
HCPCS	
E0747	Osteogenesis stimulator, electrical, noninvasive, other than spinal applications
E0749	Osteogenesis stimulator, electrical, surgically implanted

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

Definition of Terms

Congenital pseudoarthrosis: Congenital pseudarthrosis of the tibia (CPT) is a rare condition that is usually seen shortly after birth and is rarely diagnosed after the age of two. It appears as a bowing of the tibial bone and could led to a fracture if not found before the child begins to walk. Children with CPT may have poor healing ability and attempts to unite the small bone fragments can cause damage to the tibia and/or ankle joint. Congenital pseudarthrosis of the tibia has been linked to Type 1 neurofibromatosis but the exact cause of CPT is unknown.[2]

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, fracture nonunion serial radiographs (described below) show no evidence of healing. When lumped together, delayed union and nonunion are sometimes referred to as "ununited fractures."

Fracture nonunion: No consensus on the definition of fracture nonunions currently exists. One proposed definition is failure of progression of fracture healing for at least 3 consecutive months (and at least 6 months following the fracture) accompanied by clinical symptoms of delayed/nonunion such as pain, difficulty weight bearing (Bhandari et al, 2012).

The original US 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 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 individuals, 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 (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 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.

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 (i.e., closed reduction and cast immobilization).

Benefit Application

Noninvasive electrical bone growth stimulation devices may be adjudicated according to the benefits for durable medical equipment.

Evidence Review

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.

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. Individual 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.

Summary of Evidence

Noninvasive Electrical Bone Growth Stimulation

For individuals with fracture nonunion who receive noninvasive electrical bone growth stimulation, the evidence includes randomized controlled trials (RCTs) and systematic reviews of RCTs. The relevant outcomes are symptoms, change in disease status, and functional outcomes. The FDA has approved noninvasive electrical bone growth stimulation for fracture nonunions or congenital pseudoarthroses in the appendicular skeleton, based largely on studies with individuals serving as their own controls. There is also evidence from two small sham-controlled randomized trials that noninvasive electrical stimulators improve fracture healing for individuals with fracture nonunion. There are few nonsurgical options in this population, and the pre-post studies of individuals 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 with delayed fracture union who receive noninvasive electrical bone growth stimulation, the evidence includes RCTs and systematic reviews of RCTs. The 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. The 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. 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. The 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 two small RCTs. The relevant outcomes are symptoms, change in disease status, and functional outcomes. Although the results of one 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 a 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. The 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.

Ongoing and Unpublished Clinical Trials

A search of **ClinicalTrials.gov** in March 2024 did not identify any ongoing or unpublished trials that would likely influence this review.

Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from five academic medical centers while this policy was under review in 2012. Input supported the use of noninvasive electrical bone growth stimulation for the treatment of fracture nonunions or congenital pseudoarthroses of the appendicular skeleton. Input concurred that noninvasive electrical bone growth stimulation is investigational for the treatment of fresh fractures and immediate postsurgical treatment after appendicular skeletal surgery. Most reviewers considered the use of noninvasive electrical bone growth stimulation to be investigational for the treatment of delayed union, arthrodesis, or failed arthrodesis.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion 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.

Medicare National Coverage

Noninvasive stimulators are covered 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."

Regulatory Status

In 1984, the noninvasive OrthoPak Bone Growth Stimulator (BioElectron, now Zimmer Biomet) was approved by the US 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, 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. 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] As of March 2024, however, the devices remain Class 3.

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

FDA product code LOF.

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History

Date	Comments
04/14/15	New Policy. Policy replaces 7.01.529. Policy developed with literature review through November 4, 2014.
07/01/16	Annual Review, approved June 14, 2016. Policy statements rewritten for usability, intent unchanged. Policy updated with literature review through March, 2016; one reference added. Added definition of congenital pseudoarthrosis. Policy statements intent is unchanged.
07/01/17	Annual Review, approved June 6, 2017. Policy moved into new format. Policy updated with literature review through February 23, 2017; references 1-2, 8, 12, 18-19, and 21-22 added. Policy statements unchanged.
07/01/18	Annual Review, approved June 22, 2018. Policy updated with literature review through February 2018; no references added. Policy statements unchanged.
07/01/19	Annual Review, approved June 4, 2019. Policy updated with literature review through February 2019; No references added. Policy statements unchanged.
04/01/20	Delete policy, approved March 10, 2020. This policy will be deleted effective July 2, 2020 and replaced with InterQual criteria for dates of service on or after July 2, 2020.
05/06/20	Interim Review, approved May 5, 2020. This policy is reinstated immediately and will no longer be deleted or replaced with InterQual criteria on July 2, 2020.
07/01/20	Annual Review, approved June 4, 2020. Policy updated with literature review through February 2020; no references added. Pseudarthrosis added to the policy; statements otherwise unchanged.
07/02/20	Coding update. Removed CPT 20975 and HCPCS E0749.
02/01/21	Coding update. Added CPT code 20975 and HCPCS code E0749.
07/01/21	Annual Review, approved June 1, 2021. Policy updated with literature review through January 11, 2021; 1 reference added; Policy statements unchanged.
07/01/22	Annual Review, approved June 13, 2022. Policy updated with literature review through January 17, 2022; no references added; Policy statements unchanged.
07/01//23	Annual Review, approved June 12, 2023. Policy updated with literature review through January 13, 2023; no references added. Minor editorial refinements to policy

Date	Comments
	statements; intent unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
07/01/24	Annual Review, approved June 10, 2024. Policy updated with literature review through March 11. 2024; no references added; Policy statements unchanged.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2024 Premera All Rights Reserved.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.