



FEP Medical Policy Manual

FEP 7.01.07 Electrical Bone Growth Stimulation of the Appendicular Skeleton

Annual Effective Policy Date: July 1, 2024

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 trial participants, 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 "united 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).

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

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. In September 2020, FDA considered the reclassification of noninvasive electrical bone growth stimulators from Class 3 to the lower-risk Class 2 category..¹ As of March 2024, however, the devices remain Class 3.

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. Available 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 indications²⁸:

- "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

1. U.S. Food and Drug Administration (FDA). Summary Minutes: Center for Devices and Radiological Health Orthopaedic and Rehabilitation Devices Panel. 2020; <https://www.fda.gov/media/145157/download>. Accessed March 12, 2024.
2. Bhandari M, Fong K, Sprague S, et al. Variability in the definition and perceived causes of delayed unions and nonunions: a cross-sectional, multinational survey of orthopaedic surgeons. *J Bone Joint Surg Am*. Aug 01 2012; 94(15): e1091-6. PMID 22854998
3. Buza JA, Einhorn T. Bone healing in 2016. *Clin Cases Miner Bone Metab*. 2016; 13(2): 101-105. PMID 27920804
4. Ahl T, Andersson G, Herberts P, et al. Electrical treatment of non-united fractures. *Acta Orthop Scand*. Dec 1984; 55(6): 585-8. PMID 6335345
5. Connolly JF. Selection, evaluation and indications for electrical stimulation of ununited fractures. *Clin Orthop Relat Res*. 1981; (161): 39-53. PMID 6975690
6. Connolly JF. Electrical treatment of nonunions. Its use and abuse in 100 consecutive fractures. *Orthop Clin North Am*. Jan 1984; 15(1): 89-106. PMID 6607443
7. de Haas WG, Beaupr A, Cameron H, et al. The Canadian experience with pulsed magnetic fields in the treatment of ununited tibial fractures. *Clin Orthop Relat Res*. Jul 1986; (208): 55-8. PMID 3720140
8. Sharrard WJ, Sutcliffe ML, Robson MJ, et al. The treatment of fibrous non-union of fractures by pulsing electromagnetic stimulation. *J Bone Joint Surg Br*. 1982; 64(2): 189-93. PMID 6978339
9. Aleem IS, Aleem I, Evaniew N, et al. Efficacy of Electrical Stimulators for Bone Healing: A Meta-Analysis of Randomized Sham-Controlled Trials. *Sci Rep*. Aug 19 2016; 6: 31724. PMID 27539550
10. Simonis RB, Parnell EJ, Ray PS, et al. Electrical treatment of tibial non-union: a prospective, randomised, double-blind trial. *Injury*. May 2003; 34(5): 357-62. PMID 12719164
11. Barker AT, Dixon RA, Sharrard WJ, et al. Pulsed magnetic field therapy for tibial non-union. Interim results of a double-blind trial. *Lancet*. May 05 1984; 1(8384): 994-6. PMID 6143970
12. Scott G, King JB. A prospective, double-blind trial of electrical capacitive coupling in the treatment of non-union of long bones. *J Bone Joint Surg Am*. Jun 1994; 76(6): 820-6. PMID 8200888

13. Shi HF, Xiong J, Chen YX, et al. Early application of pulsed electromagnetic field in the treatment of postoperative delayed union of long-bone fractures: a prospective randomized controlled study. *BMC Musculoskelet Disord*. Jan 19 2013; 14: 35. PMID 23331333
14. Sharrard WJ. A double-blind trial of pulsed electromagnetic fields for delayed union of tibial fractures. *J Bone Joint Surg Br*. May 1990; 72(3): 347-55. PMID 2187877
15. Griffin XL, Warner F, Costa M. The role of electromagnetic stimulation in the management of established non-union of long bone fractures: what is the evidence?. *Injury*. Apr 2008; 39(4): 419-29. PMID 18321512
16. Griffin XL, Costa ML, Parsons N, et al. Electromagnetic field stimulation for treating delayed union or non-union of long bone fractures in adults. *Cochrane Database Syst Rev*. Apr 13 2011; (4): CD008471. PMID 21491410
17. Adie S, Harris IA, Naylor JM, et al. Pulsed electromagnetic field stimulation for acute tibial shaft fractures: a multicenter, double-blind, randomized trial. *J Bone Joint Surg Am*. Sep 07 2011; 93(17): 1569-76. PMID 21915570
18. Faldini C, Cadossi M, Luciani D, et al. Electromagnetic bone growth stimulation in patients with femoral neck fractures treated with screws: prospective randomized double-blind study. *Curr Orthop Pract*. 2010;21(3):282- 287.
19. Hannemann PF, Gttgens KW, van Wely BJ, et al. The clinical and radiological outcome of pulsed electromagnetic field treatment for acute scaphoid fractures: a randomised double-blind placebo-controlled multicentre trial. *J Bone Joint Surg Br*. Oct 2012; 94(10): 1403-8. PMID 23015569
20. Hannemann PF, van Wezenbeek MR, Kolkman KA, et al. CT scan-evaluated outcome of pulsed electromagnetic fields in the treatment of acute scaphoid fractures: a randomised, multicentre, double-blind, placebo-controlled trial. *Bone Joint J*. Aug 2014; 96-B(8): 1070-6. PMID 25086123
21. Martinez-Rondanelli A, Martinez JP, Moncada ME, et al. Electromagnetic stimulation as coadjuvant in the healing of diaphyseal femoral fractures: a randomized controlled trial. *Colomb Med (Cali)*. 2014; 45(2): 67-71. PMID 25100891
22. Beck BR, Matheson GO, Bergman G, et al. Do capacitively coupled electric fields accelerate tibial stress fracture healing? A randomized controlled trial. *Am J Sports Med*. Mar 2008; 36(3): 545-53. PMID 18055921
23. Borsalino G, Bagnacani M, Bettati E, et al. Electrical stimulation of human femoral intertrochanteric osteotomies. Double-blind study. *Clin Orthop Relat Res*. Dec 1988; (237): 256-63. PMID 3191636
24. Dhawan SK, Conti SF, Towers J, et al. The effect of pulsed electromagnetic fields on hindfoot arthrodesis: a prospective study. *J Foot Ankle Surg*. 2004; 43(2): 93-6. PMID 15057855
25. Petrisor B, Lau JT. Electrical bone stimulation: an overview and its use in high risk and Charcot foot and ankle reconstructions. *Foot Ankle Clin*. Dec 2005; 10(4): 609-20, vii-viii. PMID 16297822
26. Lau JT, Stamatis ED, Myerson MS, et al. Implantable direct-current bone stimulators in high-risk and revision foot and ankle surgery: a retrospective analysis with outcome assessment. *Am J Orthop (Belle Mead NJ)*. Jul 2007; 36(7): 354-7. PMID 17694182
27. Saxena A, DiDomenico LA, Widtfeldt A, et al. Implantable electrical bone stimulation for arthrodeses of the foot and ankle in high-risk patients: a multicenter study. *J Foot Ankle Surg*. 2005; 44(6): 450-4. PMID 16257674
28. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Osteogenic Stimulators (150.2). 2005; <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=65>. Accessed March 11, 2024.

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.
June 2024	Replace policy	Policy updated with literature review through March 11, 2024; no references added; Policy statements unchanged.

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.