MEDICAL POLICY

Capital BLUE

POLICY TITLE	ELECTRICAL BONE GROWTH STIMULATION OF THE APPENDICULAR SKELETON
POLICY NUMBER	MP-1.024

Effective Date:	9/1/2023

I. POLICY

Noninvasive electrical bone growth stimulation may be considered **medically necessary** as 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 or date of surgery;
- 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.

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. (See Policy Guidelines for definition of delayed union.) There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Implantable and semi-invasive electrical bone growth stimulators are considered **investigational**. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with these procedures.

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 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 that had not shown 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 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 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). 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 (i.e., closed reduction, cast immobilization).

Cross-reference:

MP 1.150 Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures
MP 6.021 Ultrasound Accelerated Fracture Healing Device

II. PRODUCT VARIATIONS TOP

This policy is only applicable to certain programs and products administered by Capital BlueCross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at:
https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies

III. DESCRIPTION/BACKGROUND TOP

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.

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

FDA product code LOF.

IV. RATIONALE

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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 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 a meaningful 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 the effects of the technology on health outcomes.

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 the effects of the technology on health outcomes.

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 the effects of the technology on health outcomes.

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 the effects of the technology on health outcomes.

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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 the effects of the technology on health outcomes.

V. DEFINITIONS

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APPENDICULAR SKELETON consists of the bones of the limbs and their girdles, attached to the axial skeleton.

AXIAL SKELETON consists of bones in the head and trunk of the human body. It is composed of five parts; the human skull, the ossicles of the inner ear, the hyoid bone of the throat, the rib cage, and the vertebral column.

CONGENITAL PSEUDARTHROSIS refers to a birth defect in the continuity of the tibia resulting in a separation or gap in the bone. The area is predisposed to fractures, which heal poorly.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital BlueCross' Provider Services or Member Services. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational; therefore not covered, implantable and semi-invasive electrical bone growth stimulation:

Procedure Codes								
20975	E0749							

Covered when medically necessary, noninvasive electrical bone growth stimulation:

Procedure Codes								
20974	E0747							

Note: Covered for all appendicular fractures with 3 months non-healing and serial radiograph confirmation.

IX. REFERENCES

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X. POLICY HISTORY

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MP 1.024	**CAC 5/27/03**
	CAC 12/2/03
	CAC 9/28/04
	CAC 9/27/05
	CAC 5/30/06
	CAC 2/27/07
	CAC 3/25/08
	CAC 5/26/09
	CAC 1/26/10 Minor Revision. Existing medically necessary policy statements modified by adding lumbar (spine) to the statements. Steroid use and current smoking habits added as another high-risk condition for non-fusion. New policy statements added that semi-invasive stimulators are investigational for lumbar spine fusion and that electrical bone-growth stimulators are investigational for use in cervical spine fusion. References updated.
	CAC 7/26/11 Adopt BCBSA. For Electrical Bone Growth Stimulation of the Appendicular Skeleton, the following indications has been removed from the policy statement: A non-healed osteotomy site, stress fractures, and treatment of Charcot foot disease (initial treatment immediately after surgical fusion. Electrical Bone Growth Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures risk criteria has been revised by deleting the information regarding multiple prior surgeries at risk for subsequent failed fusion (s). For Ultrasound Accelerated Fracture Healing Device, information was added regarding risk factors related to patient comorbidities and fracture locations that contribute to delayed fracture healing or nonunion of bones. An FEP variation was added. The Medicare variation was removed.
	1/4/12 Administrative update. Medicare variation placed on policy.
	CAC 4/24/12 Minor revision. Ultrasound accelerated fracture healing device is now considered medically necessary for delayed union in addition to fresh closed fracture and nonunion. Expanded investigational applications of electrical bone growth stimulation.
	CAC 6/4/13 Consensus review. Administrative code review complete.
	CAC 3/25/14 Minor revision. For ultrasound accelerated fracture healing device

	• Changed current tobacco use to history of smoking. • Added nonunion of previously surgically-treated fractures as a medically necessary indication • Added fresh surgically-treated closed fractures and arthrodesis or failed arthrodesis as investigational indications Added policy guidelines defining fresh fracture and delayed union. <u>For electrical bone growth stimulation of the appendicular skeleton</u> • Added clarification for compliance with non-weight bearing for fractures of pelvis and lower extremities. • Stress fractures added to investigational statement Rationale section added, References updated Added clarification for compliance with non-weight bearing for fractures of pelvis and lower extremities. Added reference to NCD 150.2 in Medicare variation. Policy coded.
	CAC 3/24/15 Consensus review. References and rationale updated. No changes to the policy statements**.** Coding reviewed.
	11/2/15 Administrative update. LCD number changed from L11501 to L33796 due to NHIC update to ICD-10.
	1/1/17 Administrative update. Product variation section updated. New diagnosis codes added effective 10/1/16.
	CAC 7/26/16 Minor revision. Title changed to Electrical Bone Growth Stimulation of the Appendicular Skeleton. The following topics were removed and are now addressed within stand-alone policies: • MP-1.150 Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures • MP-6.021 Ultrasound Accelerated Fracture Healing Device Criteria was added to the diagnosis of fracture nonunion within the first policy statement which states, “the fracture gap is 1 cm or less.” Description/Background, Policy Guidelines, Rationale and Reference sections updated. Coding reviewed/updated.
	CAC 9/26/17 Consensus review. No changes to the policy statements. References and rationale updated. Coding reviewed. Revised ICD 10 code descriptions to policy effective from 10/1/17.
	1/1/18 Administrative update. Medicare variations removed from Commercial Policies.
	6/01/18 Consensus review. Policy statements unchanged. Description/Background, Rationale and Reference sections updated.
	10/1/18 Administrative update. Revised ICD-10 codes updated effective 10/1/18
	3/20/19 Administrative update. Coding reviewed. Diagnosis note added.
	08/01/2019-Consensus review. No references added. Policy statements unchanged

	6/22/2020 Consensus review. No change to policy statement. Background, Rationale and References updated.
	3/22/2021 Consensus review. Corrected spelling of pseudarthrosis. No change to policy statement.
	5/24/2022 Consensus Review. Reference updates and coding reviewed.
	5/23/2023 Consensus review. Updated background and references. No changes to coding.

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