



Medical Policy

Electrical Bone Growth Stimulation of the Appendicular Skeleton

Table of Contents

- [Policy: Commercial](#)
- [Description](#)
- [References](#)
- [Policy: Medicare](#)
- [Policy History](#)
- [Coding Information](#)
- [Authorization Information](#)
- [Information Pertaining to All Policies](#)

Policy Number: 499

BCBSA Reference Number: 7.01.07

NCD/LCD: Local Coverage Determination (LCD): Osteogenesis Stimulators (L33796)

Related Policies

- Ultrasound Accelerated Fracture Healing Device, #[497](#)
- Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures, #[498](#)
- Bone Morphogenetic Protein, #[097](#)

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Noninvasive electrical bone growth stimulation may be **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 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 patient can be adequately immobilized and is of an age likely to comply with non-weight bearing for fractures of the pelvis and lower extremities.

INVESTIGATIONAL applications of electrical bone growth stimulation include, but are not limited to, immediate postsurgical treatment after appendicular skeletal surgery, stress fractures, or for the treatment of fresh fractures, delayed union, arthrodesis or failed arthrodesis.

Implantable and semi-invasive electrical bone growth stimulators are **INVESTIGATIONAL**.

Fresh Fracture

A fracture is most commonly defined as “fresh” for 7 days after the fracture occurs. Most fresh closed fractures heal without complications with the use of standard fracture care, ie, closed reduction and cast immobilization.

Delayed Union

Delayed union is defined as a decelerating healing process as determined by serial x-rays, 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.

Nonunion

There is not a consensus for the definition of nonunions. 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 (pain, difficulty weight bearing).¹

The original FDA labeling of fracture nonunions defined nonunions as fractures that had not shown progressive healing after at least 9 months from the original injury. 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. 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.

Medicare HMO BlueSM and Medicare PPO BlueSM Members

Medical necessity criteria and coding guidance for **Medicare Advantage members living in Massachusetts** can be found through the link below.

[Local Coverage Determinations \(LCDs\) for National Government Services, Inc.](#)

Local Coverage Determination (LCD): Osteogenesis Stimulators (L33796)

Note: To review the specific LCD, please remember to click “accept” on the CMS licensing agreement at the bottom of the CMS webpage.

For medical necessity criteria and coding guidance for **Medicare Advantage members living outside of Massachusetts**, please see the Centers for Medicare and Medicaid Services website at <https://www.cms.gov> for information regarding your specific jurisdiction.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is not required .
Commercial PPO and Indemnity	Prior authorization is not required .
Medicare HMO Blue SM	Prior authorization is not required .
Medicare PPO Blue SM	Prior authorization is not required .

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above **medical necessity criteria MUST** be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

CPT Codes

CPT codes:	Code Description
20974	Electrical stimulation to aid bone healing; noninvasive (non-operative)
20975	Electrical stimulation to aid bone healing; invasive (operative)

HCPCS Codes

HCPCS codes:	Code Description
E0747	Osteogenesis stimulator, electrical, noninvasive, other than spinal applications
E0749	Osteogenesis stimulator, electrical, surgically implanted

Description

Delayed Fracture Healing

Most bone fractures heal spontaneously over a few months postinjury. Approximately 5% to 10% of all fractures have delayed healing, resulting in continued morbidity and increased utilization of health care services.¹

There is no standard definition of a fracture nonunion.² The Food and Drug Administration (FDA) labeling for one of the electrical stimulators included in this review defined nonunion as follows: "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 a minimum of 3 months." Others have contended that nine months represents an arbitrary cutoff point that does not reflect the complicated variables present in fractures (ie, the degree of soft tissue damage, alignment of the bone fragments, vascularity, quality of the underlying bone stock). Other proposed definitions of nonunion involve three to six months from the original injury, or simply when serial radiographs fail to show any further healing. According to the FDA labeling for a low-intensity pulsed ultrasound device, "a nonunion is considered to be established when the fracture site shows no visibly progressive signs of healing." Factors contributing to a nonunion include: which bone is fractured, fracture site, the degree of bone loss, time since injury, the extent of soft tissue injury, and patient factors (eg, smoking, diabetes, systemic disease).¹

Delayed union is generally considered a failure to heal between three and nine months postfracture, after which the fracture site would be considered a nonunion. Delayed union may also be defined as a decelerating bone healing process, as identified in serial radiographs. In contrast, nonunion serial radiographs show no evidence of healing. Together, delayed union and nonunion are sometimes referred to as "united fractures." To determine fracture healing status, it is important to include both radiographic and clinical criteria. Clinical criteria include the lack of ability to bear weight, fracture pain, and tenderness on palpation.

Fractures at certain locations (eg, scaphoid, proximal fifth metatarsal) are at greater risk of delayed union due to a tenuous blood supply. Systemic factors, including immunosuppression, cancer, and tobacco use, may also predispose patients to fracture nonunion, along with certain medications (eg, nonsteroidal anti-inflammatory drugs, fluoroquinolones).

Treatment

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 six to nine 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 six to eight hours a day for three to six 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.

Summary

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.

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. The 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 pseudoarthroses in the appendicular skeleton, based largely on studies with patients serving as their controls. There is also evidence from two 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, fresh or stress fracture(s), or who have had surgery of the appendicular skeleton 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. RCTs on the delayed union of the other types 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.

Invasive Electrical Bone Growth Stimulation

For individuals who have 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 the effects of the technology on health outcomes.

Policy History

Date	Action
5/2019	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
5/2017	New references added from BCBSA National medical policy.
9/2016	Clarified coding information.
2/2015	New references added from BCBSA National medical policy.
7/2014	Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.
6/2014	BCBSA National medical policy review. New investigational indications described; medically necessary indications clarified. Effective 6/1/2014.
12/2013	Removed reference to NCD 150.2 as the LCD for Massachusetts (L11501) meets the intent of the policy. Removed ICD-9 diagnosis codes 966.49, V45.4 as these do not meet the intent of the policy.
4/2013	BCBSA National medical policy review. New investigational indications described. Effective 4/1/2013.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
6/2011	Reviewed - Medical Policy Group - Orthopedics, Rehabilitation Medicine and Rheumatology. No changes to policy statements.
4/2011	BCBSA National medical policy review. No changes to policy statements.
7/2010	Reviewed - Medical Policy Group - Orthopedics, Rehabilitation Medicine and Rheumatology. No changes to policy statements.
12/2009	BCBSA National medical policy review. Changes to policy statements.
7/2009	Reviewed - Medical Policy Group - Orthopedics, Rehabilitation Medicine and Rheumatology. No changes to policy statements.
7/2008	Reviewed - Medical Policy Group - Orthopedics, Rehabilitation Medicine and Rheumatology. No changes to policy statements.
4/2008	BCBSA National medical policy review. No changes to policy statements.
2/2008	BCBSA National medical policy review. Changes to policy statements.
7/2007	Reviewed - Medical Policy Group - Orthopedics, Rehabilitation Medicine and Rheumatology. No changes to policy statements.
6/2007	BCBSA National medical policy review. Changes to policy statements.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

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