

# Electrical and Ultrasound Bone Growth Stimulators (for Kentucky Only)

**Policy Number:** CS037KY.08  
**Effective Date:** January 1, 2024

[➔ Instructions for Use](#)

Table of Contents	Page
<a href="#">Application</a> .....	1
<a href="#">Coverage Rationale</a> .....	1
<a href="#">Definitions</a> .....	2
<a href="#">Applicable Codes</a> .....	2
<a href="#">Description of Services</a> .....	2
<a href="#">Clinical Evidence</a> .....	3
<a href="#">U.S. Food and Drug Administration</a> .....	4
<a href="#">References</a> .....	4
<a href="#">Policy History/Revision Information</a> .....	5
<a href="#">Instructions for Use</a> .....	5

Related Policies
None

## Application

This Medical Policy only applies to the state of Kentucky.

## Coverage Rationale

### Spinal Applications

#### *Invasive Electrical*

The use of an invasive spinal [Electrial Bone Growth Simulator](#) is proven and medically necessary as an adjunct to lumbar spinal fusion surgery when the following two criteria are met:

- Radiographic evidence of skeletal maturity; **and**
- Increased risk for fusion failure demonstrated by any of the following:
  - Previously failed fusion at the same site, when minimum of six months has elapsed since the last surgical procedure
  - Spinal fusion performed or to be performed at more than one level as part of a single surgery
  - Comorbid conditions associated with compromised bone healing (e.g., diabetes, obesity, osteoporosis, current tobacco use)
  - Spondylolisthesis grade II or greater

#### *Noninvasive Electrical*

The use of noninvasive spinal electrical bone growth stimulators is proven and medically necessary as an adjunct to spinal surgery under certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Durable Medical Equipment, Bone Growth Stimulators, Noninvasive.

Click [here](#) to view the InterQual® criteria.

## Non-Spinal Applications, Invasive and Noninvasive

The use of invasive or noninvasive bone growth stimulators for non-spinal applications is considered proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP:

- Durable Medical Equipment, Bone Growth Stimulators, Noninvasive
- Procedures, Bone Graft and Implantable Stimulator, Fracture Nonunion

Click [here](#) to view the InterQual® criteria.

## Definitions

**Electrical Bone Growth Stimulator:** A device (either implanted into the body or worn externally), that uses an electric field or current to stimulate the growth of bone tissue (Haglin, 2017).

- **Invasive:** The implantable current generator is surgically placed in an intramuscular or subcutaneous space, while an electrode is implanted within the fragments of bone graft at the targeted fusion site. The implanted device is usually functional for 6 to 9 months at which point the current generator is removed in a second surgical procedure, while the electrodes may or may not be removed. Implantable bone growth stimulators are used as an adjunct to spinal fusion surgery and implanted at the time of surgery.

## Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
<b>Electrical Bone Growth Stimulator: Non-Spinal (Invasive, Non-Invasive)</b>	
20974	Electrical stimulation to aid bone healing; noninvasive (nonoperative)
20975	Electrical stimulation to aid bone healing; invasive (operative)
<b>Ultrasound Bone Growth Stimulator</b>	
20979	Low intensity ultrasound stimulation to aid bone healing, noninvasive (nonoperative)

*CPT® is a registered trademark of the American Medical Association*

**Coding Clarification:** Utilize HCPCS code E0748 when reporting bone growth stimulation for all anatomical levels of the spine.

HCPCS Code	Description
E0747	Osteogenesis stimulator, electrical, noninvasive, other than spinal applications
E0748	Osteogenesis stimulator, electrical, noninvasive, spinal applications
E0749	Osteogenesis stimulator, electrical, surgically implanted
E0760	Osteogenesis stimulator, low intensity ultrasound, noninvasive

## Description of Services

Bone healing is a complex process dependent on a variety of factors. The rate of bone repair and composition of tissue varies depending on type of bone fractured, the extent of the bone and soft tissue damage, the adequacy of the blood supply, and the degree of separation between bone ends. The individual's general health and nutritional status also play a significant role in bone healing. The presence of infection may adversely affect healing. Diminished blood flow to the fracture site will often suppress the healing response; factors that can cause diminished blood flow include heavy smoking, malnutrition, diabetes, alcoholism, peripheral vascular disease, increasing age, and the use of some medications such as steroids. Other

characteristics such as high-grade trauma, high grade and open fractures, comminution of the fracture, vertical or oblique fracture pattern, and fracture displacement may also contribute to poor healing of bone (Agency for Healthcare Research and Quality [AHRQ], 2005).

Bone growth stimulation is utilized to promote bone healing in difficult to heal fractures or fusions by applying electrical or ultrasonic current to the fracture/fusion site. Ultrasonic stimulation is applied externally, while electrical stimulation can be applied either from the outside of the body (noninvasive) or from the inside of the body (invasive).

Bone growth stimulators are only indicated for use in individuals who are skeletally mature. A person is said to be skeletally mature when all bone growth is complete; the cartilage cells of the growth plate cease to proliferate, the growth plate becomes thinner, is replaced by bone, and disappears, and the epiphysis is "closed" or fused with the shaft.

## Clinical Evidence

### Electrical Bone-Growth Stimulators

Akhter et al. (2020) conducted a systematic review and meta-analysis to evaluate if postoperative electrical stimulation is more efficacious than no stimulation or placebo in promoting radiographic fusion in patients undergoing spinal fusion. The investigators searched the Cochrane Central Register of Controlled Trials (CENTRAL), EMBASE, CINAHL and MEDLINE from date of inception to current. Ongoing clinical trials were also identified, and reference lists of included studies were manually searched for relevant articles. Two reviewers independently screened studies, extracted data, and assessed risk of bias. Data were pooled using the Mantel-Haenszel method. Trialists were contacted for any missing or incomplete data. Of 1184 articles screened, 7 studies were eligible for final inclusion (n = 941). A total of 487 patients received postoperative electrical stimulation and 454 patients received control or sham stimulation. All evidence was of moderate quality. Electrical stimulation (pulsed electromagnetic fields, direct current, and capacitive coupling) increased the odds of a successful fusion by 2.5-fold relative to control. A test for subgroup interaction by stimulation type, smoking status, and number of levels fused was not significant. The investigators concluded that this systematic review and meta-analysis found moderate-level evidence supporting the use of postoperative electrical stimulation as an adjunct to spinal fusion surgery. When compared to sham, placebo-controlled, or no stimulation, patients treated with postoperative electrical stimulation have significantly greater rates of successful radiographically defined fusions. According to the investigators, these results are supported by a notably high statistically significant effect, a narrow confidence interval, and the inclusion of only high-quality randomized trials with human subjects.

Aleem et al. (2016) conducted a meta-analysis of randomized sham-controlled trials to assess the efficacy of electrical stimulation for bone healing. Outcomes were pain relief, functional improvement, and radiographic nonunion. Fifteen trials met the inclusion criteria. Four trials included patients undergoing spinal fusion, five trials evaluated fresh fracture treatment, five trials examined treatment of delayed or nonunion, and one study included patients undergoing surgical osteotomy. According to the investigators, this systematic review and meta-analysis showed that patients treated with electrical stimulation as an adjunct for bone healing experience lower rates of radiographic nonunion or persistent nonunion and have significantly less pain. The results related to pain reduction were however mainly due to one trial that evaluated electrical stimulation for spinal fusion surgery. The trials that evaluated electrical stimulation for nonunion or delayed union of long bones did not show statistically significant pain reduction nor a statistically significant difference at the level of meta-analysis between treatment and control groups for the radiographic union outcome (risk ratio for persistent nonunion compared to sham: 0.55, 95%CI: 0.29 to 1.12). The investigators also indicated that no difference was seen in functional outcomes in a limited number of trials. According to the investigators, future trials focusing on functional outcomes are needed.

A systematic review of electrical stimulation to enhance bone healing by Griffin and Bayat identified 105 clinical studies and 35 in vitro studies of the technology. Direct current was found to be effective in enhancing bone healing in spinal fusion, as supported by four studies at level of evidence 1 (randomized control trial). The authors found support for its use for nonunion fractures, but only based on level of evidence 4 (case series). Eleven studies were retrieved for capacitive coupling suggesting its effectiveness for spinal fusion but, for treating nonunions, the findings were conflicting. Studies of inductive coupling for long bones had conflicting findings. Overall, the studies, although in favor of electrical stimulation application in bone repair, displayed variability in treatment regime, primary outcome measures, follow-up times, and study design, making critical evaluation and assessment difficult (Griffin and Bayat, 2011).

A randomized controlled trial by Foley et al. (2008) tested the efficacy of PEMF stimulation to support cervical fusion in 323 participants with compressed cervical nerve root and symptomatic radiculopathy appropriate to the compressed root that had failed to respond to nonoperative management. While the group randomized to PEMF showed a significantly higher fusion rate than the control group (83.6% vs. 68.6%,  $p = 0.0065$ ) at six months, the group difference disappeared at 12 months post-surgery (92.8% vs. 86.7%,  $p = 0.1129$ ). Additionally, the study failed to show any group difference in patient-centered outcome such as pain scores, neck disability index, or functional status at 6 or 12 months. The authors concluded that although PEMF stimulation appeared to hasten bone healing in this randomized trial, it did not result in a significant advantage in terms of ultimate fusion rates or clinical outcomes for cervical fusion.

### **Clinical Practice Guidelines**

Current specialty society guidelines support the use of noninvasive electrical bone growth stimulators following spinal fusion. They suggest that when choosing a device capacitive coupling stimulation (CCS) versus pulsed electromagnetic field stimulation (PEMFS), the surgical approach and procedure should be taken into consideration.

### **American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS)**

A 2014 update to the (AANS) and (CNS) guidelines for bone growth stimulators as an adjunct for lumbar spinal fusion found no new evidence that conflicted with their original 2005 recommendations supporting the use of CCS to enhance fusion rates in patients at high risk of nonunion undergoing posterior lumbar fusion and PEMFS in high-risk patients following interbody fusion (Kaiser et al., 2014).

### **The North American Spine Society (NASS)**

NASS coverage policy recommendations agree with AANS recommendations for spinal indications. According to this document, the current evidence is insufficient to support a coverage recommendation for the use of low intensity pulsed ultrasound or combined magnetic field technology for spinal use, in their opinion, electrical stimulation for augmentation of spinal fusion is indicated for all regions of the spine in individuals at high risk for pseudoarthrosis with specific criteria (i.e., fusion of 3 or more vertebrae, revision spinal fusion, smokers who cannot stop smoking prior to fusion [e.g., trauma], and in the presence of comorbidities). Electrical stimulation is not indicated for a primary spinal fusion without risk factors, spinal fusion of two vertebral levels without risk factors, presence of malignancy, as an adjunct for primary bone healing of a spinal fracture, and as nonsurgical treatment of an established pseudoarthrosis (NASS, 2016).

## **U.S. Food and Drug Administration (FDA)**

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

The FDA regards bone growth stimulators as significant-risk (Class III) devices. Because the list of products used for bone growth stimulation is extensive, refer to the following website for more information and search by product name in the Device Name field on either the 510(k) page or on the Premarket Approvals page using Product Codes LOE (for stimulator, invasive bone growth), LOF (for stimulator, bone growth, non-invasive), or LPQ (for ultrasound bone growth stimulators):

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>. (Accessed August 22, 2023)

## **References**

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Kaiser MG, Eck JC, Groff MW, et al. Guideline update for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 17: Bone growth stimulators as an adjunct for lumbar fusion. *J Neurosurg Spine*. 2014 Jul;21(1):133-9.

North American Spine Society. *Electrical Stimulation for Bone Healing. Coverage Policy Recommendations*. August 2016.

## Policy History/Revision Information

Date	Summary of Changes
01/01/2024	<b>Supporting Information</b> <ul style="list-style-type: none"><li>Updated <i>Clinical Evidence</i> and <i>References</i> sections to reflect the most current information</li><li>Archived previous policy version CS037KY.07</li></ul>

## Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare uses InterQual® for the primary medical/surgical criteria, and the American Society of Addiction Medicine (ASAM) for substance use, in administering health benefits. If InterQual® does not have applicable criteria, UnitedHealthcare may also use UnitedHealthcare Medical Policies, Coverage Determination Guidelines, and/or Utilization Review Guidelines that have been approved by the Kentucky Department for Medicaid Services. The UnitedHealthcare Medical Policies, Coverage Determination Guidelines, and Utilization Review Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.