Electrical and Ultrasound Bone Growth Stimulators (for Nebraska Only)

Policy Number: CS037NE.O
Effective Date: August 1, 2022

Instructions for Use

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Related Policies
None

Application

This Medical Policy only applies to the State of Nebraska.

Coverage Rationale

The use of invasive or noninvasive spinal electrical bone growth stimulator 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

The use of invasive spinal electrical bone growth stimulators is unproven and not medically necessary for the treatment of all other indications due to insufficient evidence of efficacy and/or safety.

For noninvasive electrical or ultrasound bone growth stimulators, refer to the Nebraska Department of Health and Human Services, Chapter 7-000 Durable Medical Equipment, Prosthetics, Orthotics and Medical Supplies (DMEPOS).

Definitions

Delayed Union: A fracture has not healed within the expected time period. The fact that a bone is delayed in its union does not mean that it will become a non-union.

Electrical Bone Growth Stimulation: The use of a device (either implanted into the body or worn externally), that uses an electric field or current to stimulate the growth of bone tissue.

- 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.
- Non-Invasive: An external power source generates a weak electrical current to the target sites using either pulsed electromagnetic fields, capacitive coupling or combined magnetic fields.

Fracture Union: The point at which the fractured bone has regained sufficient strength and stiffness to function as a weightbearing structure without external support.

Non-Union Fracture: The result of an arrest in the healing process and is defined by the following three findings:

- Motion at the fracture site
- Radiographic evidence showing the persistence of the fracture line without bridging callus
- Incomplete progression toward radiographic healing in the expected length of time for the given bone and further healing not expected

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 federal, state, or contractual requirements 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
Electrical Bone Growth Stimulator: Non-Spinal (Invasive, Non-Invasive)	
20974	Electrical stimulation to aid bone healing; noninvasive (nonoperative)
20975	Electrical stimulation to aid bone healing; invasive (operative)
Ultrasound Bone Growth Stimulator	
20979	Low intensity ultrasound stimulation to aid bone healing, noninvasive (nonoperative)

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, non-invasive

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 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

A Hayes report evaluated the evidence for noninvasive electrical bone growth stimulators (EBGS) for spinal fusion or foot and ankle indications. The initial report from 2016 indicated that the evidence evaluating noninvasive EBGS in adults found that this technology is safe and suggests that it may improve fusion rates and health outcomes for patients undergoing lumbar or lumbosacral spinal fusion who are at high risk for failed fusion such as smoking or multilevel disease. According to the report, the body of evidence evaluating noninvasive EBGS for lumbar or lumbosacral spinal fusion is moderate in quality. The initial report from 2016 indicated that noninvasive EBGS may also be of benefit as an adjunctive treatment to promote healing in patients undergoing cervical spinal fusion, foot and ankle arthrodesis, and treatment of osteochondral lesions of the talus. According to the report, the body of evidence evaluating noninvasive EBGS for cervical spinal fusion, foot and ankle arthrodesis, and osteochondral lesions of the talus is low in quality. The 2021 updated Hayes review indicates there has been no change to the evidence (Hayes, 2016; updated 2021).

Caliogna et al. (2021) conducted an extensive review of the recent literature of the signaling pathways modulated by pulsed electromagnetic fields (PEMFs) and PEMFs clinical application for bone healing. A review of the literature was performed on two medical electronic databases (PubMed and Embase). Three authors performed the evaluation of the studies and the data extraction. All studies for this review were selected following these inclusion criteria: studies written in English, studies available in full text and studies published in peer-reviewed journal. The investigators concluded that the data reported in the literature give a solid base for the clinical application of PEMFs; unfortunately, the selected electromagnetic field parameters are very different (frequency, waveform, and amplitude), thus preventing the possibility to carry out accurate analysis. To date, there is a great heterogeneity of the PEMFs physical parameters used, both for in vitro and in vivo studies for bone healing. As a consequence of lack of standardized experimental guidelines, controlled trials resulted in non-comparable and inconclusive data. The investigators indicted that further biology studies and clinical trials with clear and standardized parameters (intensity, frequency, dose, duration, type of coil) are required to clarify the precise dose-response relationship and to understand the real applications in clinical practice of PEMFs for bone healing.

Peng et al. (2020) conducted a systematic review and meta-analysis to evaluate the effect of pulsed electromagnetic field (PEMF) on bone healing in patients with fracture. The investigators searched CNKI, Wan Fang, VIP, EMbase, PubMed, CENTRAL, Web of Science, Physiotherapy Evidence Database, and Open Grey websites for randomized controlled trials (published before July 2019 in English or Chinese) comparing any form of PEMF to sham. Reference lists were also searched. Related data were extracted by two investigators independently. The bias risk of the articles and the evidence strength of the outcomes were evaluated. Twenty-two studies were eligible and included in the analysis (n = 1,468 participants). The pooled results of 14 studies (n = 1,131 participants) demonstrated that healing rate in PEMF group was 79.7%, and that in the control group was 64.3%. PEMF increased healing rate by the Mantel-Haenszel analysis, relieved pain by the inverse variance analysis, and accelerated healing time by the inverse variance analysis. Moderate quality evidence suggested that PEMF increased healing rate and relieved pain of fracture, and very low-quality evidence showed that PEMF accelerated healing time. According to the investigators, a limitation of this systematic review and meta-analysis was that the literature was insufficient to analyze whether PEMF has an impact on bone mineral density (BMD) and functional outcome. Even for bone healing, different effects may be achieved by PEMF treatments with different parameters (frequency, intensity). Though the determination of effective intensity and frequency is important for each clinical application, there was not enough literature to analyze them, and it is difficult to discuss the dose-response relationship. In the future, more high-quality trials are needed to analyze the effectiveness of PEMF and to identify the best parameters, dose, and duration of PEMF.

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.

Shi et al (2013) reported a randomized sham-controlled trial that included 58 patients with delayed union of surgically-reduced long-bone fractures (femur, tibia, humerus, radius or ulna).12 Delayed union was defined as a failure to heal after at least 16 weeks and not more than 9 months following surgical reduction and fixation of the fracture. Patients with fracture nonunion, defined as failure to heal after more than 9 months, were excluded from the study. Treatment with 8 hours of pulsed electromagnetic field therapy (PEMF) per day was stopped when no radiographic progression was observed over 3 months or when union was achieved, with union defined as no pain during joint stressing or during motion at the fracture site and callus bridging for three out of four cortices on blinded assessment. Three months of treatment resulted in a slight, but not statistically significant, improvement in the rate of union between PEMF-treated patients and controls (38.7% vs. 22.2%). The success rate was significantly greater with PEMF (77.4% vs. 48.1%) after an average of 4.8 months of treatment. The time to union was not significantly different between PEMF (4.8 months; range, 2-12) and sham controls (4.4 months; range, 2-7).

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, 2014).

North American Spine Society (NASS)

The 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 pseduoarthrosis with specific criteria (i.e., fusion of three 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 pseduoarthrosis. (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 device name section: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed October 7, 2021)

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Policy History/Revision Information

Date	Summary of Changes
08/01/2022	**Coverage Rationale** • Replaced language indicating "the use of invasive or noninvasive spinal electrical bone growth stimulator is *considered* proven and medically necessary as an adjunct to lumbar spinal fusion surgery when the [listed] criteria are met" with "the use of invasive or noninvasive spinal electrical bone growth stimulator is proven and medically necessary as an adjunct to lumbar spinal fusion surgery when the [listed] criteria are met" **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Removed *CMS* section • Archived previous policy version CS037NE.N

Instructions for Use

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