

Electrical Bone Growth Stimulation (Spine)

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Introduction

Electrical bone growth stimulation for the spine is addressed in this guideline.

Health Equity Consideration

Health equity is the highest level of health for all individuals; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which individuals are born, grow, live, work, and age. Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include the following: safe housing, transportation, and neighborhoods; racism, discrimination, and violence; education, job opportunities, and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

Criteria

- Noninvasive electrical bone growth stimulation may be considered medically necessary following spinal fusion surgery in patients at high risk for pseudarthrosis with **one** or more of the following risk factors for fusion failure:
 - Alcohol Use Disorder (AUD)
 - Body mass index (BMI) > 30
 - Diabetes, renal disease, or other metabolic diseases when bone healing is likely to be compromised
 - Glucocorticoid dependent
 - Meyerding Grade III or worse lumbar/lumbosacral spondylolisthesis
 - Multi-level spinal fusion including three (3) or more vertebrae
 - Nutritional deficiency/malnutrition
 - One or more previously failed spinal fusion(s)
 - Osteoporosis or osteopenia (T-score of <-1.0) on a recent (within one year) DEXA
 - Severe anemia
 - Smoking history
 - Immunocompromised status

- Noninvasive electrical bone growth stimulation is considered medically necessary as a treatment for patients with failed spinal fusion when **both** of the following criteria are met:
 - A minimum of 6 months has passed since the date of the original surgery
 - Serial plain X-rays or appropriate imaging studies confirm there is no evidence of progression of healing/consolidation of the spinal fusion for 3 months during the later portion of the 6 month post-fusion surgery period
- Urgent/emergent conditions for spine fusion surgery are exceptions to the above timelines for noninvasive electrical bone growth stimulation excluding primary or metastatic neoplastic disease.

Not Medically Necessary

Noninvasive electrical bone growth stimulation is considered not medically necessary for **all** of the following:

- Acute or chronic lumbar spondylolysis (pars interarticularis defect) with or without spondylolisthesis
- Failed cervical or lumbar disc arthroplasty
- Spinal malignancy
- As nonsurgical treatment of an established pseudarthrosis

Evidence Discussion

In a 2023 prospective, multicenter study (Weinstein et al.) evaluating adjunctive pulsed electromagnetic field therapy following lumbar spinal fusion, individuals with at least one risk factor for pseudarthrosis demonstrated a high rate of successful fusion and significant clinical improvement. Radiographic assessment at 12 months showed a fusion success rate of 88% overall, with fusion rates of 88.5% among individuals with one risk factor, 87.5% among those with two or more risk factors, and 82.3% among those with three or more risk factors. Statistically significant improvements from baseline were observed across multiple patient-reported outcome measures, including the Oswestry Disability Index, Visual Analog Scale scores for back and leg pain, Short Form-36, and EuroQol-5D scores, with all improvements reaching p values < 0.001. No device-related serious adverse events were reported, and the therapy was well tolerated during the required home use period. The authors concluded that non-invasive pulsed electromagnetic field stimulation used in the home setting was associated with a high likelihood of successful fusion and meaningful improvements in pain, function, and quality of life, even among individuals at elevated risk for fusion failure. Study limitations included the lack of a randomized control group, reliance on historical comparisons rather than concurrent controls, and potential selection bias inherent to prospective cohort design, which limited definitive causal inference.

A 2024 prospective, multicenter study by Lansford et al. evaluating adjunctive pulsed electromagnetic field stimulation following cervical spinal fusion, individuals with at least one risk factor for pseudarthrosis demonstrated high rates of successful fusion and significant functional improvement. Radiographic assessment at 12 months showed a fusion success rate of 90% overall, with fusion achieved in 91.7% of individuals with one risk factor, 89% of those with two or more risk factors, and 90.9% of those with three or more risk factors. Statistically significant improvements from baseline were observed across all evaluated patient-reported outcome measures, including the Neck Disability Index, Visual Analog Scale scores for neck and arm pain, Short Form-36, and EuroQol-5D scores, with all comparisons reaching p values < 0.001 . No serious device-related adverse events were reported, and treatment adherence in the home setting was acceptable. The authors concluded that postoperative non-invasive pulsed electromagnetic field stimulation was associated with a high likelihood of cervical fusion success and meaningful improvements in pain, function, and quality of life among individuals at elevated risk for fusion failure. Study limitations included the absence of a randomized control group, reliance on a single treatment cohort without concurrent comparison, and potential selection bias inherent to the prospective observational design, which limited the ability to establish definitive causality.

A 2024 systematic review and meta-analysis by Luo et al. evaluated the effect of electrical bone growth stimulation on spinal fusion outcomes across randomized controlled trials and cohort studies involving individuals undergoing spinal fusion surgery. A total of 16 studies ($n=2151$) were included, with non-invasive stimulation modalities consisting of pulsed electromagnetic field stimulation, capacitive coupling, and direct current stimulation. Meta-analysis demonstrated that electrical stimulation was associated with a statistically significant increase in successful spinal fusion compared with control or placebo treatment. The pooled fusion rate among individuals receiving electrical stimulation was 86.8% compared with 73.7% in control groups. Subgroup analyses showed improved fusion rates with pulsed electromagnetic field stimulation. Randomized controlled trials alone also showed higher fusion rates in stimulation groups compared with controls. The authors concluded that electrical bone growth stimulation used as an adjunct to spinal fusion surgery increased the likelihood of radiographic fusion regardless of stimulation modality, supporting its role in postoperative fusion management. Study limitations included substantial heterogeneity across included studies, variability in fusion assessment methods, mixed study designs with differing risk of bias, and limited consistency in reporting stimulation protocols, which reduced the ability to determine the relative effectiveness of individual stimulation modalities.

Electrical bone growth stimulation is intended to enhance spinal fusion in individuals at increased risk of nonunion or pseudarthrosis, and impaired bone metabolism is a well-established contributor to failed fusion. While osteoporosis ($T\text{-score} \leq -2.5$) has traditionally been recognized as a risk factor, evidence indicated that osteopenia ($T\text{-score} > -2.5$)

score<-1.0) is also independently associated with adverse fusion outcomes. The North American Spine Society (NASS) recognized compromised bone quality, including both osteoporosis and osteopenia, as clinically relevant factors that negatively impact fusion success and emphasized that bone mineral density represents a continuum of risk rather than a strict diagnostic threshold (North American Spine Society [NASS], n.d.). Hills et al. (2019) identified low bone mineral density and metabolic or endocrine disorders as contributors to pseudarthrosis, noting that even moderate reductions in bone density impair bone-healing physiology. Additionally, Khalid et al. (2020) demonstrated that adult individuals with osteopenia or osteoporosis undergoing single-level lumbar fusion experienced significantly higher rates of pseudarthrosis and revision surgery compared with individuals with normal bone density, with osteopenia conferring increased risk independent of other factors. Collectively, this evidence supported expanding eligibility for electrical bone growth stimulation to include individuals with osteoporosis or osteopenia (T-score<-1.0) documented on a DEXA scan within one year.

Codes Addressed in This Guideline

HCPSC Code	Description
E0748	Osteogenesis stimulator, electrical, non-invasive, spinal applications

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