09-E0000-22

Original Effective Date: 06/15/00

Reviewed: 01/22/26

Revised: 02/15/26

Subject: Non-Invasive Electrical Bone Growth Stimulators (EBGS)

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions	Related Guidelines
Other	References	Updates			

DESCRIPTION:

An electrical bone growth stimulator is a device that provides electrical stimulation to augment bone repair. A noninvasive electrical stimulator is characterized by an external power source which is attached to a coil or electrodes placed on the skin, or on a cast or brace over a fracture or fusion site. 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 per day until healing occurs, or up to 9 months. In contrast, pulsed electromagnetic fields are delivered via treatment coils that are placed over the skin and are worn for 6 to 8 hours per 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.

Summary and Analysis of Evidence: Coric et al 2018 evaluated the effect of pulsed electromagnetic field (PEMF) treatment on subjects at increased risk for pseudoarthrosis after anterior cervical discectomy and fusion (ACDF) procedures. Two evaluations were performed that compared fusion rates between PEMF stimulation and a historical control (160 subjects) from the FDA investigational device exemption (IDE) study: a post hoc (PH) analysis of high-risk subjects from the FDA study (PH PEMF); and a multicentre, open-label (OL) study consisting of 274 subjects treated with PEMF (OL PEMF). Fisher's exact test and multivariate logistic regression was used to compare fusion rates between PEMF-treated subjects and historical controls. In separate comparisons of PH PEMF and OL PEMF groups to the historical control group, PEMF treatment significantly ($p < 0.05$, Fisher's exact test) increased the fusion rate at six and 12 months for certain high-risk subjects who had at least one clinical risk factor of being elderly, a nicotine user, osteoporotic, or diabetic; and for those with at least one clinical risk factor and

who received at least a two- or three-level arthrodesis. The authors concluded that adjunctive pulsed electromagnetic field (PEMF) treatment can be recommended for patients who are at high risk for pseudoarthrosis. Aleem et al (2016) conducted a meta-analysis of randomized sham-controlled trials to establish the efficacy of electrical stimulation for bone healing. Trials randomizing patients to electrical or sham stimulation for bone healing were identified. Outcomes were pain relief, functional improvement, and radiographic nonunion. Two reviewers assessed eligibility and risk of bias, performed data extraction, and rated the quality of the evidence. Fifteen trials met our inclusion criteria. Moderate quality evidence from 4 trials found that stimulation produced a significant improvement in pain (mean difference (MD) on 100-millimeter visual analogue scale = -7.7 mm; 95% CI -13.92 to -1.43; p = 0.02). Two trials found no difference in functional outcome (MD = -0.88; 95% CI -6.63 to 4.87; p = 0.76). Moderate quality evidence from 15 trials found that stimulation reduced radiographic nonunion rates by 35% (95% CI 19% to 47%; number needed to treat = 7; p < 0.01). Patients treated with electrical stimulation as an adjunct for bone healing have less pain and are at reduced risk for radiographic nonunion; functional outcome data are limited and requires increased focus in future trials.

POSITION STATEMENT:

Noninvasive electrical bone growth stimulation (EGBS) with an FDA-approved device **meets the definition of medical necessity** for the following:

Non-Spinal

Fracture non-union or congenital pseudoarthrosis, when **ALL** of the following are met:

- At least 3 months have passed since the date of fracture
- Serial radiographs (a minimum of 2 sets of radiographs, each including multiple views of the fracture site, separated by a minimum of 90 days) have confirmed that no progressive signs of healing have occurred; **AND**
- The fracture gap is 1cm or less; **AND**
- The member can be adequately immobilized; **AND**
- The member is able to comply with non-weight bearing for fractures of the pelvis and lower extremities

Spinal

As an adjunct to spinal fusion surgery, for those at high risk for fusion failure, defined as any of the following:

- One or more previously failed fusion(s)
- Grade III or worse spondylolisthesis
- Fusion performed at more than one level
- Diabetes
- Renal disease
- Alcoholism

- Steroid use
- Current tobacco use

Noninvasive electrical bone growth stimulation **meets the definition of medical necessity** as a treatment of members with failed spinal fusion (Failed spinal fusion is defined as a spinal fusion that has not healed at a minimum of 6 months after the original surgery, as evidenced by serial x-rays over a course of 3 months).

Noninvasive electrical bone growth stimulation is considered **experimental or investigational** for ANY of the following. The evidence is insufficient to determine the effects of the technology on health outcomes.

- Immediate post-surgical treatment
- Stress fractures
- Treatment of fresh fractures
- Arthrodesis (spinal) in the absence of high risk factors
- As a stand-alone non-surgical salvage of failed spinal arthrodesis
- As an adjunct to cervical spinal fusion in the absence of high risk for fusion failure
- As an adjunct to thoracic spinal fusion in the absence of high risk for fusion failure.

BILLING/CODING INFORMATION:

CPT Coding:

20974	Electrical stimulation to aid bone healing; noninvasive (non-operative)

HCPCS Coding:

E0747	Osteogenic stimulator, electrical, non-invasive, other than spinal applications (e.g., Physio-Stim)
E0748	Osteogenic stimulator, electrical, non-invasive, spinal applications (e.g., Spinal-Stim)

LOINC Codes:

The following information may be required documentation to support medical necessity: Physician history and physical, physician treatment notes, treatment plan, radiology and surgical reports.

Documentation Table	LOINC Codes	LOINC Time Frame Modifier Code	LOINC Time Frame Modifier Codes Narrative
Physician history and physical	28626-0,	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.

Attending physician visit note or treatment notes	18733-6	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Treatment plan	18776-5	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Radiology study reports	18726-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Physician operative note (surgical report)	28573-4	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products:

The following National Coverage Determination (NCD) was reviewed on the last guideline reviewed date: Osteogenetic Stimulation; Electrical Osteogenic (150.2) Stimulators located at cms.gov.

The following Local Coverage Determination (LCD) was reviewed on the last guideline reviewed date: Osteogenic Stimulation (L33796) located at cms.gov.

DEFINITIONS:

Arthrodesis: surgical fixation of the joint by a procedure designed to cause fusion of the joint surfaces by promoting the generation of bone cells.

Congenital: present at birth; not acquired.

Delayed union: a fracture that exhibits 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.

Fresh fracture: most commonly defined as "fresh" for 7 days after the fracture occurs, most heal without complications with the use of standard fracture care (e.g., closed reduction and cast immobilization).

Nonunion: fracture site shows no visible progressive signs of healing after 3 months or more, as confirmed by serial radiographs (i.e., bone healing has ceased).

Pseudoarthrosis (pseudarthrosis): a pathologic entity characterized by the loss or reduction of mineral elements of a weight-bearing long bone, followed by bending and pathologic fracture, with inability to form normal callus, leading to the existence of the "false joint" that gives the condition its name.

Spondylolisthesis: forward displacement of one vertebra over another, usually of the fifth lumbar over the body of the sacrum, or of the fourth lumbar over the fifth, usually due to a developmental defect.

RELATED GUIDELINES:

Invasive Electrical Bone Growth Stimulator (EBGS), 02-20000-22

Ultrasound Osteogenesis Stimulators, 09-E0000-32

OTHER:

Other names used to report non-invasive electrical bone growth stimulators (EBGS):

Note: The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Orthofix Spinal-Stim®

REFERENCES:

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3. American Academy of Orthopaedic Surgeons (AAOS). OrthoInfo. Nonunions. March 2014.
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6. Ciombor DM, Aaron RK. The role of electrical stimulation in bone repair. Foot Ankle Clin. 2005 Dec;10(4):579-93, vii. doi: 10.1016/j.fcl.2005.06.006. [Abstract]
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10. 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. Journal of Neurosurgery: Spine. Journal of Neurosurgery Spine 2014; 21(1): 133-139.
11. Mackenzie D, Veninga FD. Reversal of delayed union of anterior cervical fusion treated with pulsed electromagnetic field stimulation: case report. South Med J. 2004 May;97(5):519-24. [Abstract].
12. Medicare Jurisdiction J-C CGS Administrators, LLC 18003-DME MAC: Local Coverage Determination (LCD): Osteogenesis Stimulators (L33796), 01/01/24.
13. Mollon B, da Silva V, Busse JW, et al. Electrical stimulation for long-bone fracture-healing: a meta-analysis of randomized controlled trials. J Bone Joint Surg Am. 2008; 90(11):2322-2330.
14. Morone MA, Feuer H. The use of electrical stimulation to enhance spinal fusion. Neurosurgery Focus 2002; 13(6): Article 5.
15. North American Spine Society (NASS). NASS Coverage Policy Recommendations: Electrical Stimulation for Bone Healing, 2016.
16. Shi HF, Xiong J, Chen YX et al. Early application of pulsed electromagnetic field in the treatment of postoperative delayed union of long-bone fractures: a prospective randomized controlled study. BMC Musculoskelet Disord. 2013; 14:35.
17. Simmons JW, Mooney V, Thacker I. Pseudarthrosis after lumbar spine fusion: nonoperative salvage with pulsed electromagnetic fields. American Journal of Orthopedics 2004; 33(1): 27-30.
18. U.S. Food and Drug Administration; Guidance Document for Industry and CDRH Staff for the Preparation of Investigational Device Exemptions and Pre-market Approval Applications for Bone Growth Stimulator Devices.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 01/22/26.

GUIDELINE UPDATE INFORMATION:

06/15/00	New Medical Coverage Guideline.
08/23/01	MCG reviewed – no changes.
03/15/03	MCG reviewed – no changes.
03/15/04	Reviewed; no change in coverage statement.
03/15/05	Scheduled review; added: “delayed union after 90 days” as a covered indication; added ICD-9 diagnosis codes and definitions.
03/15/06	Scheduled review; no change in coverage statement; correction made to ICD-9 diagnosis code 996.44; added congenital pseudoarthrosis (ICD-9 755.8) as a covered indication.
08/15/07	Review, coverage statement maintained, guideline reformatted, references updated.
03/15/09	Scheduled review; position statement unchanged; references updated.
11/15/09	Revision of Position Statement to include additional risk factors.
10/15/10	Revision; related ICD-10 codes added; formatting changes.
03/15/11	Scheduled review; position statement unchanged; references updated.
09/15/11	Revision; formatting changes.

05/11/14	Revision: Program Exceptions section updated.
04/15/15	Scheduled review. Revised description, position statement, and definitions. Updated references and reformatted guideline.
05/15/16	Reviewed; Added headers to position statement: “non-spinal” and “spinal”. Added position statement for noninvasive electrical bone growth stimulation as a treatment for failed lumbar spinal fusion. Deleted “or failed arthrodesis” from arthrodesis experimental or investigational. Added “(spinal) in the absence of high risk factors to arthrodesis experimental or investigational. Added “as a stand-alone non-surgical salvage or failed spinal arthrodesis to experimental or investigational. Updated program exceptions. Added Orthrofix Spinal-Stim® to other section. Updated references.
03/15/19	Review: add “lumbar” to spinal fusion surgery. Add “as an adjunct to cervical and thoracic spinal fusion” (experimental or investigational). Updated references.
03/15/20	Review/revision. Removed “lumbar” from spinal medical necessity position statement. Added “in the absence of high risk for fusion failure” to the experimental or investigational position statement. Updated references.
09/15/22	Review; no change in position statement. Updated references.
06/15/24	Review; no change in position statement. Updated references.
02/15/26	Position statements maintained.