CLINICAL MEDICAL POLICY	
Policy Name:	Electrical Bone Growth Stimulators for the Spine (Osteogenesis Stimulators)
Policy Number:	MP-067-MD-PA
Responsible Department(s):	Medical Management
Provider Notice/Issue Date:	03/01/2023; 04/01/2022; 03/19/2021; 04/20/2020; 05/06/2019; 04/15/2018
Effective Date:	05/01/2022; 04/19/2021; 05/18/2020; 05/06/2019; 04/15/2018
Retirement Effective Date:	04/01/2023
Next Annual Review:	N/A
Revision Date:	01/18/2023; 01/19/2022; 01/20/2021; 01/15/2020; 01/16/2019
Products:	Highmark Wholecare℠ Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 12

Policy History

Date	Activity
04/01/2023	Retirement Effective date
01/18/2023	QI/UM Committee review
01/18/2023	Urgent Review: Policy to be retired, spinal EBGS is now covered in policy MP-070-MD-PA "*Electrical Bone Growth Stimulators (Noninvasive/Invasive, Spinal, & Ultrasound)*".
05/01/2022	Provider Effective date
03/02/2022	PARP Approval
01/19/2022	QI/UM Committee review
01/19/2022	Annual Review: No changes to clinical criteria. Revised Procedures section wording. Updated Summary of Literature and Reference Sources sections.
04/19/2021	Provider Effective Date
03/05/2021	PARP Approval
01/20/2021	QI/UM Committee review
01/20/2021	Annual Review: Updated Summary of Literature, removed outdated Rationale section, updated NASS quoted recommendation and Reference sections
05/18/2020	Provider effective date
02/21/2020	PARP approval
01/15/2020	QI/UM Committee Review

01/15/2020	Annual Review: Under Procedure section removed the age requirement and skeletal maturity criteria; add 1.A.10 criteria related to FDA approval; in the DME section replaced the word authorization with eligible; corrected several typographical errors; the Operational Guidelines were edited to remove the age requirements; added diagnosis codes M43.26, M43.27 & Q76.2; deleted diagnosis codes M48.05 – M48.07 & M51.04 – M51.9; updated Summary of Literature and References.
05/06/2019	Provider effective date
02/15/2019	Removed the E/I status in the operational guidelines and replaced it with a NMN status, changed the age requirement to postpayment.
02/07/2019	PARP approval
01/17/2019	QI/UM Committee Review
01/17/2019	Annual Review Revisions: There is no change to the position statement and criteria; updated the formatting in the 'Procedures' section; updated the formatting of the summary of literature; updated literature in the rationale; added an updated Hayes reference; hyperlinks were removed from the references.
04/15/2018	Provider effective date
02/28/2018	PARP approval
01/24/2018	QI/UM Committee Review Approval
12/28/2017	Initial policy developed

Disclaimer

Highmark Wholecare℠ medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

Policy Statement

Highmark Wholecare℠ may provide coverage under the medical-surgical and DME benefits of the Company's Medicaid products for medically necessary invasive and non-invasive electrical bone growth stimulators as an adjunct to lumbar spinal fusion procedures.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

(Current applicable Pennsylvania HealthChoices Agreement Section V. Program Requirements, B. Prior Authorization of Services, 1. General Prior Authorization Requirements.)

Definitions

Prior Authorization Review Panel (PARP) – A panel of representatives from within the Pennsylvania Department of Human Services who have been assigned organizational responsibility for the review, approval and denial of all PH-MCO Prior Authorization policies and procedures.

Non-invasive bone growth stimulators – A device that uses pulsed-electromagnetic fields, capacitative coupling or combined magnetic fields to generate a weak electric current through the target site.

Invasive bone growth stimulators – A device that requires surgical implantation of a direct current generator in an intramuscular or subcutaneous space while an electrode is implanted within the fragments of bone graft at the fusion site.

Arthrodesis (spinal fusion) – The surgical binding together or immobilization of a joint by fusion of adjacent bones.

Pseudarthrosis – The failed fusion resulting from poor bone healing. This condition may be due to the patient tissue that does not heal the bone well, inadequate bone placed into the fusion area, excessive motion across the fusion area limiting healing, infection, and suboptimal alignment or fusion technique.

Multilevel Spinal Fusion – The procedure is a spinal fusion that involves three or more vertebrae (e.g., L3-L5, L4-S1, etc.).

Failed Spinal Fusion – A minimum of 6 months has elapsed since the last surgery with an additional 3 months of serial x-ray evidence for a total of 9 months.

Spondylolisthesis – A condition in which one bone in the spine (vertebra) slips out of position. The bone can slide forward or backward over the bone below it. The condition is caused by one or more small joints around the spine that allow the bone to move out of line. Malfunctioning joints can be caused by congenital defect, previous traumatic event, stress fractures, infection, or arthritis.

Cathode – A negatively charged electrode by which electrons enter an electrical device. The opposite of a cathode is an anode, which is positively charged.

Capacitative Coupling Electric Field (CCEF) – A type of stimulation that involves two electrodes placed on the skin over the fusion site and connected to an external battery-powered device. The batteries are changed daily, and the patient is encouraged to use the device as much as possible (24 hours per day).

Pulsed Electromagnetic Field (PEMF) – A type of stimulation that requires coils (usually embedded in a brace) that produces a time-varying magnetic field around the area of the desired fusion. Patients are generally instructed to wear the device for 3 to 8 hours per day.

Combined Magnetic Fields (CMF) – A type of stimulation that delivers a time-varying magnetic field by superimposing the time-varying field onto an additional static magnetic field. This device involves 30 minutes of treatment daily for 9 months.

Direct Current Stimulation (DCS) – A type of stimulation that uses electrodes implanted within or very close to the location of the desired fusion. Modern devices consist of a sealed electrical source that is implanted at the time of surgery.

Invasive Osteogenesis Stimulators – Also known as implantable electrical stimulators, utilizing a direct current that is delivered internally via implanted electrodes to a non-healing fracture or bone fusion site.

Noninvasive Osteogenesis Stimulators – Stimulating device that utilizes treatment coils situated externally around a fracture using an external poser supply.

Procedures

1. Invasive and *non-invasive electrical bone growth stimulators (EBGS) for the spine are considered medically necessary as an adjunct to lumbar spinal fusion surgery for patients at high risk for pseudarthrosis when ALL of the following criteria are met:
    A. The patient has ONE of the following clinically documented conditions:
        1) One or more previously failed lumbar spinal fusion(s) at the same site; OR
        2) A multilevel spinal fusion surgery is to be performed; OR
        3) Diabetes; OR
        4) Renal disease; OR
        5) Grade III or worse spondylolisthesis; OR
        6) Current smoking tobacco use; OR
        7) Alcoholism; OR
        8) Steroid use associated with low bone mass or bone loss; OR
        9) Severe osteoporosis which is demonstrated on radiographs; AND
    B. The EBGS device is approved by the FDA and being utilized for an FDA approved indication

    ***Note**: The noninvasive EBGS is considered medically necessary for the treatment of a failed lumbar fusion where a minimum of 9 months has elapsed since the original surgery, as evidenced by serial x-rays.

2. Contraindications
    A. Invasive and non-invasive spinal EBGS is contraindicated in patients with implanted electrical devices, such as:
        1) Cardiac pacemakers; OR
        2) Implantable cardioverter-defibrillator; OR
        3) Subcutaneous implantable cardioverter-defibrillator; OR
    B. Invasive and non-invasive EBGS is contraindicated in the presence of an external or internal fixation device constructed from magnetic materials; OR
    C. There are unknown effects associated with electromagnetic stimulation in pregnant and nursing women.

3. When the EBGS treatment is not covered for the spine
    Spinal EBGS is not covered for conditions other than those listed above because the scientific evidence has not been established. Non-covered conditions include, but are not limited to, ANY of the following:
    - Invasive, semi-invasive, and non-invasive EBGS as an adjunct to cervical and thoracic spinal fusion surgery
    - As an adjunct to failed cervical and thoracic spinal fusion

- Semi-invasive EBGS as an adjunct to lumbar spinal fusion and for failed lumbar spinal fusion
- Ultrasound stimulators
- Cardiac pacemakers
- Implantable cardioverter-defibrillator
- Subcutaneous implantable cardioverter defibrillator
- Stress fractures
- Fresh fractures
- Pathological fractures due to bone pathology, tumor, or malignancy
- Spondylolysis (also known as pars inter-articularis fracture)
- Osteoarthritis and rheumatoid arthritis
- Patients with mental or physical conditions that will preclude compliance instructions

4. DME
   The invasive and non-invasive spinal EBGS devices (HCPCS code E0748) is classified as a DME rental or purchase item and may be subject to prior authorization requirements.
   The non-invasive EBGS devices are reimbursed in:
   A. The office setting to a medical supplier DME; OR
   B. The home setting to a home health DME or medical supplier DME.

   A patient is eligible for <u>one</u> spinal EBGS when the patient meets the medical necessity guidelines listed above.

5. Post-payment Audit Statement
   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Wholecare℠ at any time pursuant to the terms of your provider agreement.

6. Place of Service
   EBGS spinal therapies (invasive/non-invasive) are typically performed in an outpatient setting. The place of service may provide coverage of invasive EBGS to be performed in the inpatient setting in special circumstances including, but not limited to, an adjunct to lumbar spinal fusion surgery.

7. Related Policies
   - MP-068-MD-PA Ultrasound Bone Growth Stimulators
   - MP-070-MD-PA Noninvasive Electrical Bone Growth Stimulators (Osteogenesis Stimulators)

Governing Bodies Approval

Invasive spinal EBGS devices include, but are not limited to:
- OsteoStim® (Electro-Biology, Inc.) was FDA approved in 1986.
- Biomet SpinalPak® was FDA approved in 1999 as a capacitive coupling system for the use of adjunct therapy to primary lumbar spinal fusions at 1 or 2 levels.
- SpF ® Implantable Spinal Stimulator by Zimmer-Biomet was approved by the FDA in 1987.

Non-invasive spinal EBGS devices include but are not limited to:

- Spinal-Stim Lite® by Orthofix, Inc. was FDA approved in 1996 as a spinal adjunct to the Physio-Stim® made by Orthofix, Inc. The Spinal-Stim Lite® device was approved to increase the probability of fusion success and as a nonoperative treatment for the salvage of failed spinal fusion, where a minimum of 9 months has elapsed since the last surgery.
- DJO SpinaLogic® was FDA approved in 1994 as a combined magnetic field portable device. The device is secured with a belt around the waist.
- EBI Bone Healing System® by Biolectron was FDA approved in 1979 and indicated for nonunions, failed fusions, and congenital pseudoarthroses. The device is secured with a belt around the waist.

The use of the EBGS therapy device outside of listed FDA guidelines will require approval from a Medical Director on a case-by-case basis.

Summary of Literature

Of the estimated 7.9 million fractures that occur annually in the United States, approximately 5–10% have either delayed or impaired healing. Of the 600,000 fractures with delayed healing, nearly 100,000 progress to nonunion. The United States Food and Drug Administration (FDA) defines a nonunion as, "a fracture that has not completely healed within 9 months of injury, with serial radiographs demonstrating no progression of healing during the final three months." However, in clinical practice, there is a considerable variability for what is considered a nonunion, with definitions of nonunion ranging from 2–12 months (Buza & Einhorn, 2016).

The American Academy of Orthopedic Surgeons (2014) indicates several factors that can increase the risk of the formation of a nonunion bone fracture including:

- Use of tobacco or nicotine in any form (smoking, chewing tobacco, and use of nicotine gum or patches) inhibits bone healing and increase the chance of a nonunion
- Older age
- Severe anemia
- Diabetes
- A low vitamin D level
- Hypothyroidism
- Poor nutrition
- Medications including anti-inflammatory drugs such as aspirin, ibuprofen, and prednisone. The physician and patient should always discuss the risks and benefits of using these medications during fracture healing
- Infection
- A complicated break that is open or compound

For bone healing to happen, the bone needs adequate stability and blood supply. Good nutrition also plays a role in bone healing.

- Stability - All treatment of broken bones follows one basic rule: the broken pieces must be put back into position and prevented from moving out of place until they heal. Some fractures can be held in position with a cast. Some fractures require surgical fixation with devices like screws, plates, rods and frames.
- Blood supply - Blood delivers the components required for healing to the fracture site. These include oxygen, healing cells, and the body's own chemicals necessary for healing (growth factors). The

blood supply to the injured bone usually comes back on its own during the healing period (AAOS, 2014).

The diagnosis of a nonunion is generally based on both clinical and radiological parameters. Pain, loss of function, and tenderness to palpation - with or without fracture site mobility - are clinical signs which may suggest nonunion. Methods used to diagnose delayed or nonunion fractures can include radiograph, CT scan, ultrasound, MRI, or nuclear imaging (Nicholson, Yapp, Simpson, 2021).

Electrical stimulation of bone has been touted as an effective and noninvasive method for enhancing bone healing, and treating fracture nonunion (Kuzyk, Schemitsch 2009). There has been an increasing amount of poor outcomes with spinal fusion procedures generated from research and development in electronegativity and the electrical potential that serves as a critical cue in activating bone deposition, remodeling and formation (MacEwan, 2016). Electrical bone growth stimulation technologies were created to respond to failed spinal fusion procedures. Invasive and non-invasive spinal EBGS are used as an adjunct to spinal fusion surgery to increase the patient's chances of obtaining a solid spinal fusion. Unlike bone graft harvesting, EBGS devices are less invasive, and the complications associated with grafting do not exist (Buza, 2016). Non-invasive, external EBGS devices can be used immediately after surgery or when spinal fusion failure is identified. Direct current stimulation (DCS) devices were the first devices used for EBGS following lumbar fusion (Resnick, 2005). DCS can artificially charge bone matrix and induce local bone growth (MacEwan, 2016). The advantage of using invasive EBGS over non-invasive EBGS is the inability for the patient to remove the device, therefore displaying 100% patient compliance, and the full benefit of the treatment can be obtained. The implantable electrodes give constant stimulation. It has been shown that there is an increased risk due to implantable leads and their unknown electromagnetic effect for pregnant women and patients that have pacemakers and defibrillators (Sherman, 2002).

Cervical Spine Fusion

Foley et al. published results from the industry-sponsored investigational device exemption trial of pulsed electromagnetic field (PEMF) stimulation as an adjunct to anterior cervical discectomy and fusion (ACDF) with anterior cervical plates and allograft interbody implants. The trial presented results using the Cervical-Stim device by Orthofix and received premarket approval from the FDA in 2004. Out of 323 patients randomized in the trial, 163 patients had PEMF stimulation and 160 patients had no stimulation. The patients were active smokers (164 patients) or were undergoing multilevel ACDF (192 patients). The efficacy in the trial was measured by radiographic analysis at 1, 2, 3, 6, and 12 months (Foley, 2008).

At six-month follow-up, the PEMF group and the control group fusion rates were 65.6% and 56.3%, respectively, with no significant difference. The FDA analysis for premarket approval indicated that the results at 6 months were statistically different in sensitivity analysis performed with the last observation carried forward or with all missing data imputed as nonfusion. At twelve-month follow-up, the PEMF group and the control group fusion rates were 92.8% and 86.7%; these rates did not have a significant difference (Foley, 2008).

Lumbar Spinal Fusion

The evidence for invasive and non-invasive methods of spinal EBGS as an adjunct to lumbar spine fusion surgery includes systematic reviews, randomized controlled trials (RCTs), and societal and association recommendations. Due to differing physiological and biomechanical forces, there are distinct differences between anterior and posterior fusions to weigh during comparative analysis on the effectiveness of the devices (Morone, 2002).

Two relevant RCTs evaluated the use of invasive EBGS for lumbar fusion surgery in patients at high risk of fusion failure. One study measured instrumented spinal fusion and the other study measured non-instrumented spinal fusion. Both studies showed improved fusion with electrical stimulation and supported the conclusion of improved functional outcomes with the use of EBGS devices. The RCTs consisted of the following:

- Rogozinski & Rogozinski reported the outcomes of two consecutive series of patients undergoing posterolateral lumbar fusions (PLF) with autologous bone graft and pedicle screw fixation. In the first group, 41 patients were treated without EBGS, while the second group of 53 patients was treated with invasive EBGS. The patients that received the invasive EBGS reported a 96% fusion rate compared to the 85% fusion rate in the non-EBGS group (Rogozinski & Rogozinski, 1996).
- Kaiser et al. published radiographic and function outcomes from a 2-year multicenter RCT to determine the impact of DCS on non-instrumented lumbar fusion for patients 60 years of age and older. The RCT contained 107 patients that presented with a variety of spinal degenerative disorders and were undergoing single or multilevel PLFs. The patients were split up into two randomized groups—one group included a cohort without DCS, and the other group included a cohort with DCS insertion. The results for DCS patients demonstrated significant improvement in functional outcomes and decreased pain scores, which are beneficial effects on lumbar fusion in older patients (Kaiser, 2014).

Although the studies had some risk for bias due to differential dropout rates, both studies showed improved fusion with electrical stimulation on blinded intermediate measures of radiographic fusion.

Three relevant RCTs assessed the use of non-invasive electrical stimulation for lumbar spinal fusion surgery in patients at high risk of fusion failure. The three studies demonstrated high success rates in the group that received the electrical stimulation compared to the placebo groups. The studies performed by Mooney and Linovitz excluded patients with severe osteoporosis, and the Goodwin study excluded patients that had osteoporosis with an unspecified severity level. The RCTs consisted of the following:

- Mooney performed a study that randomized 195 patients undergoing initial attempts at interbody lumbar fusions with or without fixation—one group received PEMF stimulation, and one group did not receive PEMF stimulation. The active treatment group had a success rate of 92% compared to 65% in the placebo group (Mooney, 1990).
- Goodwin et al. performed a study that randomized 179 patients undergoing lumbar spinal fusions (with and without instrumentation) into two groups—one group received capacitative coupled electrical stimulation (CCEF) and one group did not receive the CCEF. There was an overall successful fusion rate of 84.7% among the group that actively received the CCEF electrical stimulation compared to a rate of 64.9% for the group that did not receive the CCEF electrical stimulation (Goodwin, 1999).
- Linovitz et al. performed a study that randomized 201 patients undergoing 1- or 2- level posterolateral fusion into two groups—one group received active electrical stimulation through a combined magnetic field (CMF) device, and one group did not receive the CMF. The active group had an overall successful fusion rate of 64%, and the placebo-device group had a success rate of 43% (Linovitz, 2002).

A meta-analysis of 33 articles (17 preclinical, 16 clinical) was reported on the use of electrical stimulation with spinal fusion (Cottrill et al, 2019). The review did not report on the anatomic level of the spinal fusion surgeries. The authors concluded that direct current stimulation improved fusion rates in both preclinical and clinical studies, inductive coupling stimulation improved fusion rates in the clinical studies only and

capacitive coupling stimulation was not effective at increasing fusion. A subanalysis of the clinical studies found that the use of electric stimulation increase fusion rates in patients with difficult-to-fuse spines, in patients who smoke and those that underwent multilevel fusions. It was noted that additional research is needed to analyze the cost-effectiveness of these devices.

A 2020 systematic review and meta-analysis regarding the efficacy of electrical stimulation for spinal fusion aimed to determine if postoperative electrical stimulation is more efficacious than no stimulation or placebo in promoting radiographic fusion in patients undergoing spinal fusion. The search identified 1184 articles. After excluding 195 duplicates, a total of 989 titles and abstracts were screened and 9 articles (7 studies) were eligible for our systematic review and meta-analysis. Thus, seven studies were included with a total of 941 patients, of which 487 patients received postoperative electrical stimulation and 454 patients received placebo or sham stimulation. 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 (Akhter, et al., 2020).

Practice Guidelines and Position Statements

In 2016, the North American Spine Society (NASS) issued a coverage recommendation for EBGS. The recommendation supports the use of pulsed electromagnetic field (PEMF) stimulation devices, as an adjunct to spinal fusion. The policy recommends use of electrical stimulation for fusion healing in all regions of the spine, including lumbar regions (BusinessWire, 2016). :

The American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS) released guidelines in 2005 that evaluated literature on bone growth stimulation for EBGS as an adjunct for lumbar fusion (Kaiser, 2014).

The 2005 AANS and CNS guidelines stated that there were class II and III evidence:

> "…to support the use of direct current stimulation or [capacitative coupled stimulation] for enhancing fusion rates in high-risk patients undergoing lumbar PLF. A beneficial effect on fusion rates in patients not at 'high risk' has not been convincingly demonstrated, nor has an effect been shown for these modalities in patients treated with interbody fusion. There is limited evidence both for and against the use of PEMFS for enhancing fusion rates following PLF. Class II and III medical evidence supports the use of PEMFS for promoting arthrodesis following interbody fusion. Although some studies have purported to demonstrate functional improvement in some patient subgroups, other studies have not detected differences. All of the reviewed studies are significantly flawed by the use of a four-point patient satisfaction scale as the primary outcome measure. This outcome measure is not validated. Because of the use of this flawed outcome measure and because of the conflicting results reported in the better-designed studies that assess functional outcome, there is no consistent medical evidence to support or refute use of these devices for improving patient outcomes."

The AANS and CNS updated the guidelines in 2014 indicating that there was no evidence published after their 2005 guidelines that conflicts with the previous recommendations on bone growth stimulation.

> "…The use of DCS is recommended as an option for patients younger than 60 years of age, since a positive effect on fusion has been observed. A single low-level study demonstrated a positive impact of PEMFS on patients undergoing revision surgery for pseudarthrosis, but this single study is insufficient to recommend for or against the use of PEMFS in this patient population. DCS and

CCES may be considered in patients at high risk for pseudarthrosis who are undergoing PLF, while PEMFS may be considered in a similar patient population undergoing an interbody fusion."

There are no semi-invasive EBGS devices that have been approved or cleared by the FDA for clinical uses. The therapy is considered experimental and investigational due to the absence of FDA-approved semi-invasive stimulators. The use of invasive and non-invasive EBGS devices in children is not covered, due to the lack of studies that have identified or assessed the use of EBGS in children.

The use of the PEMF devices for inflammatory arthritis and immunocompromised (e.g., undergoing chemotherapy and radiation therapy to the spine, Hypogammaglobulinemia, granulocytopenia, acquired immune deficiency syndrome, chronic granulomatous disease) comorbidities is not considered medically necessary, due to the lack of studies that have identified or assessed the use of EBGS for specific conditions related to inflammatory arthritis and immunocompromised comorbidities.

According to the Orthofix product labeling information, safety and effectiveness of EBGS has not been established for the following patients:

- Patients that are pregnant or nursing;
- Patients lacking skeletal maturity;
- Patients that have a mental or physical condition that precludes compliance with the physician and device instructions;
- Patients that have one of the following conditions:
    - Osseous or ligamentous spinal trauma
    - Spondylitis
    - Paget's disease
    - Moderate to severe osteoporosis
    - Metastatic cancer
    - Patients that have implantable defibrillators or demand pacemakers

Coding Requirements

Procedure Codes

CPT Code	Description
20974	Electrical stimulation to aid bone healing; non-invasive (nonoperative)
20975	Electrical stimulation to aid bone healing; invasive (operative)
HCPCS Code	**Description**
E0748	Osteogenesis stimulator, electrical, non-invasive, spinal applications
E0749	Osteogenesis stimulator, electrical, surgically implanted

Diagnosis Codes

ICD-10 Code	Description
M43.15	Spondylolisthesis, thoracolumbar region
M43.16	Spondylolisthesis, lumbar region
M43.17	Spondylolisthesis, lumbosacral region
M43.26	Fusion of the spine, lumbar region
M43.27	Fusion of the spine, lumbosacral region

M96.0	Pseudarthrosis after fusion or arthrodesis
Q76.2	Congenital spondylolisthesis

Reimbursement

Participating facilities will be reimbursed per their Highmark Wholecare℠ contract.

Reference Sources

Business Wire. Orthofix Announces NASS Coverage Policy Recommendations for Electrical Bone Growth Stimulators, October 24, 2016. Accessed on December 9, 2020.

Buza JA, Einhorn T. Bone healing in 2016. Clinical Cases in Mineral and Bone Metabolism, 13(2): 101-105, 2016. New York, USA. Accessed on August 3, 2017.

Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) Osteogenic Stimulators (150.2). Effective date April 27, 2005. Implementation date August 1, 2005. Accessed on December 20, 2021.

Foley KT, Mroz TE, Arnold PM, et al. Randomized, prospective, and controlled clinical trial of pulsed electromagnetic field stimulation for cervical fusion. Spine J. May-Jun 2008; 8(3):436-442. Accessed on August 4, 2017.

Goodwin CB, Brighton CT, Guyer RD, et al. A double-blind study of capacitively coupled electrical stimulation as an adjunct to lumbar spinal fusions. Spine. July 1, 1999; 24(13):1349-1356; discussion 1357. Accessed on August 7, 2017.

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 and lumbar fusion. Journal of Neurosurgery: Spine, Vol 21, July 2014. Accessed on December 9, 2020.

Linovitz RJ, Pathria M, Bernhardt M, et al. Combined magnetic fields accelerate and increase spine fusion: a double-blind, randomized, placebo controlled study. Spine (Phila Pa 1976). Jul 1 2002; 27(13):1383-1389; discussion 1389. PMID 12131732. Accessed on August 7, 2017.

Li S, Yu B, Zhou D, et al. Electromagnetic fields for treating osteoarthritis. Cochrane Database Syst Rev. 2013; 12:CD003523. PMID 24338431 Accessed on January 9, 2018.

MacEwan MR, Talcott MR, Moran DW, et al. Novel spinal instrumentation to enhance osteogenesis and fusion: a preliminary study. Journal of Neurosurgery: Spine, 25:318-327, September 2016. Accessed on August 2, 2017.

Mooney V. A randomized double-blind prospective study of the efficacy of pulsed electromagnetic fields for interbody lumbar fusions. Spine (Phila Pa 1976). Jul 1990; 15(7):708-712. Accessed on August 7, 2017.

Morone MA, Feurer H. The use of electrical stimulation to enhance spinal fusion. December 2002. Neurosurg Focus 13 (6): Article 5. Accessed on August 7, 2017.

Pennsylvania Department of Human Services. Technology Assessment Group (TAG) Coverage Decisions. Managed Care Operations Memorandum: OPS # 02/2015-001. Accessed on July 7, 2017.

Resnick DK, Choudhri TF, Dailey AT, et al. Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine; Part 17: bone growth stimulators and lumbar fusion. Journal of Neurosurgery: Spine, Vol 2, June 2005. Accessed on August 3, 2017.

Rogozinski A, Rogozinski C. Efficacy of implanted bone growth stimulation in instrumented lumbosacral spinal fusion. Spine (Phila Pa 1976). Nov 1 1996; 21(21):2479-2483. PMID 8923635. Accessed on August 4, 2017.

Sherman JE. How an Electrical Bone Growth Stimulator Helps with Spine Fusion. Spine-health: Trusted Information for Back Pain, September, 24, 2002. Accessed on July 31, 2017.

Spinal-Stim® Instructional Manual. Orthofix, Inc. U.S.A. Edition. November 11, 2014. Accessed on August 7, 2017.

U.S. Food and Drug Administration. Summary of Safety and Effectiveness Data: Cervical-Stim Model 505L Cervical Fusion System. 2004. Accessed on January 8, 2018.

Cottrill E, Pennington Z, Ahmed AK, Lubelski D, Goodwin ML, Perdomo-Pantoja A, Westbroek EM, Theodore N, Witham T, Sciubba D. The effect of electrical stimulation therapies on spinal fusion: a cross-disciplinary systematic review and meta-analysis of the preclinical and clinical data. Journal of Neurosurgery: Spine. Vol 31 (6): December 2019; 775-921. Accessed on December 19, 2019.

Akhter S, Qureshi A, Aleem I. et al. Efficacy of Electrical Stimulation for Spinal Fusion: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. Scientific Reports, No. 10, Article Number 4568. March 12, 2020. Accessed on December 9, 2020.

American Academy of Orthopaedic Surgeons (AAOS). OrthoInfo. Diseases & Conditions Nonunion. March 2014. Accessed on December 20, 2021.

Nicholson JA, Yapp LZ, Keating JF, Simpson AHRW. Monitoring of fracture healing. Update on current and future imaging modalities to predict union. Injury. Volume 52, Supplement 2. Pages S29-S34, ISSN 0020-1383. June 2021. Accessed on December 20, 2021.

Kuzyk PR, Schemitsch EH. The science of electrical stimulation therapy for fracture healing. Indian J Orthop. ;43(2):127-131. doi:10.4103/0019-5413.50846. April – June 2009. Accessed on December 20, 2021.