

Electrical Bone Growth Stimulation- Spinal

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Disclaimer

Highmark Health Options 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 Health Options may provide coverage under the medical-surgical and DME benefits of the Company's Medicaid products for medically necessary invasive and noninvasive 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.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations

DEFINITIONS

Noninvasive Bone Growth Stimulators – A device that uses pulsed-electromagnetic fields, capacitive 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 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.

Capacitive 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.

Serial Radiographs – Two or more sets of appropriate imaging studies separated by a minimum of 90 days or three months, confirming that clinically significant fracture healing has not occurred.

POLICY POSITION

1. Prior authorization is required.
2. Medical necessity guidelines

The invasive and noninvasive electrical bone growth stimulator (osteogenesis stimulator) is considered medically necessary as an adjunct to lumbar spinal fusion surgery in patients at high risk for pseudarthrosis when the following criteria are met:

- The patient is 18 years of age or older; OR
- The patient demonstrates proof of skeletal maturity (e.g., bone age study); AND
- The patient has one of the following clinically documented conditions:
 - One or more previously failed spinal fusion(s) at the same site; OR
 - A multilevel spinal fusion surgery is to be performed, OR
 - Diabetes; OR
 - Renal disease; OR
 - Grade III or worse spondylolisthesis; OR
 - Current smoking tobacco use; OR
 - Alcoholism; OR
 - Steroid use associated with low bone mass or bone loss; OR
 - Severe Osteoporosis which is demonstrated on radiographs.

3. Medical necessity guidelines

The noninvasive electrical bone growth stimulator (osteogenesis stimulator) is considered medically necessary for the treatment of a failed lumbar fusion where a minimum of 9 months has elapsed since the last surgery.

4. Contraindications

- Invasive and noninvasive electrical bone growth stimulator (EBGS) is contraindicated in patients with implanted electrical devices, such as:
 - Cardiac pacemakers; OR
 - Implantable cardioverter-defibrillator; OR
 - Subcutaneous implantable cardioverter-defibrillator; OR
- Invasive and noninvasive EBGS is contraindicated in the presence of an external or internal fixation device constructed from magnetic materials; OR
- There are unknown effects associated with electromagnetic stimulation in pregnant and nursing women.

5. When an invasive and noninvasive EBGS is not covered for the spinal indications

EBGS is not covered for conditions other than those listed above because the scientific evidence has not been established. Noncovered conditions include but are not limited to the following:

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

6. DME

The invasive and noninvasive EBGS devices (E0748) is classified as a DME rental or purchase item and may be subject to prior authorization requirements.

The noninvasive EBGS devices are reimbursed in:

- The office setting to a medical supplier DME; OR
- The home setting to a home health DME or medical supplier DME.

A patient will have authorization for one electrical bone growth stimulator when the patient meets the medical necessity guidelines above.

7. Post-payment audit statement

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

8. Place of service

Electrical bone growth stimulator therapies (invasive/noninvasive) are typically performed in an outpatient setting. The place of service may provide coverage of invasive electrical bone growth stimulators to be performed in the inpatient setting in special circumstances including, but not limited to, an adjunct to lumbar spinal fusion surgery.

GOVERNING BODIES APPROVAL

Invasive 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.

Noninvasive 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 Bioelectron was FDA approved in 1979 and indicated for nonunions, failed fusions, and congenital pseudoarthroses. The device is secured with a belt around the waist.

Additional information is available at:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm124105.htm>.

ELIGIBLE PROCEDURE CODES

CPT Codes	Description
20974	Electrical stimulation to aid bone healing; noninvasive (nonoperative).
20975	Electrical stimulation to aid bone healing; invasive (operative).
E0748	Osteogenesis stimulator, electrical, noninvasive, spinal applications.

ELIGIBLE DIAGNOSIS CODES

Codes						
M43.15	M43.16	M43.17	M48.05	M48.06	M48.061	M48.062
M48.07	M51.04	M51.05	M51.06	M51.14	M51.15	M51.16
M51.17	M51.24	M51.25	M51.26	M51.27	M51.34	M51.35

M51.36	M51.37	M51.44	M51.45	M51.46	M51.47	M51.84
M51.85	M51.86	M51.87	M51.9	M96.0	M43.18	M43.19
M43.23	M43.24	M43.25	M43.26	M43.27		
M43.28	Q74.1	Q74.2	Q74.3	Q74.4	Q74.5	Q74.6
Q74.7	Q74.8	Q74.9	Q76.2	S62.001		

SUMMARY OF LITERATURE

There are an estimated 7.9 million bone fractures that occur each year in the United States (Hayes, 2016).

Most fractures will heal with standard nonsurgical or surgical treatment, but 5% to 10% of fracture cases encounter delayed or impaired healing which can require additional action (Hayes, 2016).

A portion of the fracture cases that encounter problems with bone healing; include fractures of the spine. When a patient goes through surgical intervention for a spinal fracture, a spinal fusion process is the start of osteogenesis which promotes the growth of bony tissue and unites the bone graft pieces into a solid union of bone. The fracture cases that encounter complications in bone healing undergo pseudarthrosis (failed spinal fusion), which occurs following arthrodesis (spinal fusion). Pseudarthrosis is a common long-term complication of lumbar arthrodesis (Hayes, 2016). According to Dr. MacEwan et al. (2016), instrumented arthrodesis continues to exhibit high failure rates in patients that undergo multilevel lumbar fusion and in patients with one of the following high-risk factors: pseudarthrosis, smoking tobacco, diabetes, older age, alcoholism, infection, taking medications such as steroid use, or patients with a diagnosis of Grade III (or worse) spondylolisthesis (Sherman, 2002).

There is an increasing number 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 noninvasive 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). Noninvasive EBGs delivers an electrical current to the site of fusion by using one of the following technologies: capacitive coupling electric field (CCEF), pulsed electromagnetic fields (PEMF), or combined magnetic fields (CMF) (Hayes, 2017). The noninvasive, external device can be used immediately after surgery or when spinal fusion failure is identified. Semi-invasive EBGs uses needle-like electrodes placed through the skin. Invasive electrical stimulators (IES) are cathodes that are surgically implanted into a soft pocket of tissue next to the fracture site, distributing a production of direct current stimulation (DCS) (Hayes, 2017). DCS devices were the first devices used for electrical bone growth stimulation following lumbar fusion (Resnick, 2005). DCS can artificially charge bone matrix and induce local bone growth (MacEwan, 2016). The invasive electrical stimulation is intended to motivate the growth of bone for bone healing and arthrodesis (Hayes, 2017). The advantage of using invasive electrical stimulators over noninvasive electrical stimulators is the inability for the patient to remove the device, therefore displaying 100% patient compliance, and full benefit of treatment can be obtained. The implantable electrodes give constant stimulation, but there is increased risk due to implantable leads and their unknown electromagnetic effect for pregnant women and patients that have pacemakers and defibrillators (Sherman, 2002).

RATIONALE

The evidence review was created in July 2017 through January 2018 and includes all of the most current literature. The most recent literature update was performed.

CERVICAL SPINE FUSION

Foley et al. (2008) published results from the industry-sponsored investigational device exemption trial of 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 (Foley, 2008). Out of 323 patients randomized in the trial, 163 patients had PEMF stimulation and 160 patients had no stimulation (Foley, 2008). 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.

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 (Foley, 2008). 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 (BC Idaho, 2017). 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). According to Hayes (2016) there was no improved cervical fusion in patients at high risk of fusion failure who received electrical stimulators at twelve months. Patient compliance data was monitored by the device and assessed at each visit but the compliance data was not reported in the published article. Hayes, Inc. (2018) has maintained a C rating for noninvasive EBGs as adjunct to standard cervical spinal fusion in adult patients that are at high risk for failed fusion.

Foley et al. (2008) published results from an industry-sponsored investigational device exemption trial which describes results from an individual device, Cervical-Stim (Orthofix). The trial had methodologic limitations and the efficacy of electrical stimulation in the cervical spine has not been established. The evidence is insufficient to determine the effects of the technology on the patient health outcomes.

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 PEMF devices as an adjunct to spinal fusion surgery (NASS, 2016). The following practice guidelines summarize the NASS position:

1. "For augmentation of spinal fusion in any and all regions of the spine including occipital-cervical, cervical, cervicothoracic, thoracic, thoracolumbar, lumbar and lumbosacral spinal regions in patients at high-risk for the development of pseudarthrosis (i.e., nonunion) who exhibit one or more of the following:
 - Are undergoing spinal fusion of two or more motion segments (3 vertebrae)
 - Are undergoing a revision spinal fusion (e.g., repeat surgery for a previously unhealed fusion attempt)
 - Are smokers who cannot stop smoking in preparation for fusion due to the nature of the underlying condition (e.g., acute traumatic fracture)
 - Exhibit one or more of the following comorbidities when undergoing primary lumbar fusion:
 - Diabetes
 - Inflammatory arthritis (e.g., rheumatoid arthritis) that has required long-term corticosteroid therapy
 - Immunocompromised (e.g., undergoing chemotherapy and radiation therapy to the spine, Hypogammaglobulinemia, granulocytopenia, acquired immune deficiency syndrome, chronic granulomatous disease)
 - Systemic vascular disease

- Osteopenia or osteoporosis
2. In the lumbar spine, the following forms of electrical stimulation are indicated in high-risk patients with the specific techniques outlined. In all other regions of the spine, coverage for the same indications is recommended although there is less supporting evidence.
 - DCS [direct current stimulation: electrodes implanted within or very close to the location of the desired fusion] and CCS [capacitance coupling stimulation; two electrodes placed on the skin over the fusion site] for posterolateral fusion using autograft and extender
 - PEMFS [pulsed electromagnetic field stimulation: coils that produce a time-varying magnetic field around the area of the desired fusion] for lumbar interbody fusion.”

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 EGBS 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 indicated 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 EGBS 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 noninvasive EGBS devices in children is not covered; due to the lack of studies that have identified or assessed the use of EGBS 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 covered; due to the lack of studies that have identified or assessed the use of EGBS for specific conditions related to inflammatory arthritis and immunocompromised comorbidities.

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

1. Patients that are pregnant or nursing;
2. Patients lacking skeletal maturity;

3. Patients that have a mental or physical condition that precludes compliance with the physician and device instructions;
4. 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.

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POLICY UPDATE HISTORY

09/28/2022	Approved in Medical Policy Committee
10/2022	Approved in QI/UM