MEDICAL POLICY

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MEDICAL POLICY DETAILS	
Medical Policy Title	**Bone Growth Stimulators**
Policy Number	**1.01.53**
Category	**Contract Clarification**
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Product Disclaimer	• *Services are contract dependent; if a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

I. **ELECTRICAL BONE GROWTH STIMULATION**

A. Based upon our criteria and assessment of the peer-reviewed literature, **noninvasive** electrical bone growth stimulation has been medically proven to be effective and, therefore, is considered **medically appropriate** for the following indications:

1. Infantile non-union;
2. Failed joint fusion secondary to failed arthrodesis of the ankle or knee;
3. The treatment is for **non-union secondary to trauma** of the bones of the **appendicular skeleton**, including the humerus, ulna, radius, carpals, metacarpals, femur, tibia, fibula, tarsals, metatarsals, phalanges, scapula, clavicle, pelvis and patella. Coverage will only be available to patients who meet **ALL** of the following criteria:
   a. Three months or more have elapsed since the injury or initial treatment;
   b. At least two serial radiographs in the preceding three-month period which confirmed that no progressive signs of healing have occurred;
   c. The fracture gap is one centimeter or less; **and**
   d. The patient can be adequately immobilized and, when appropriate, is likely to comply with non-weight bearing.

B. Based upon our criteria and assessment of the peer-reviewed literature, **invasive** (inserted at the time of surgery) or **noninvasive** (beginning at any time from the time of surgery until up to six months after surgery) electrical bone growth stimulation is considered **medically appropriate** for **spinal fusion surgery** in individuals who are at high risk for pseudoarthrosis and who have **ANY** of the following risk factors for fusion failure:

1. One or more previous failed spinal fusions;
2. Multi-level fusion involving three or more vertebrae (e.g., L3-L5, L4-S1, etc.);
3. Meyerding Grade III or worse lumbar/lumbosacral spondylolisthesis;

4. Smoking history;
5. Alcohol use disorder;
6. Diabetes, renal disease, or other metabolic diseases when bone healing is likely to be compromised;
7. Nutritional deficiency/malnutrition;
8. Osteoporosis defined as a T-score of less than -2.5 on a recent (within one year) DEXA;
9. Body Mass Index (BMI) greater than 30;
10. Severe anemia;
11. Glucocorticoid dependent;
12. Immunocompromised status.

C. Based upon our criteria and assessment of the peer reviewed literature, noninvasive electrical bone growth stimulation may be considered **medically appropriate** as a treatment for individuals with **failed spinal fusion** when **BOTH** of the following criteria are met:
   1. A minimum of six months has passed since the date of the original surgery; **and**
   2. Serial radiographs or appropriate imaging studies confirm that there is no evidence of progression of healing/consolidation of the spinal fusion for three months during the latter portion of the six-month post-fusion surgery period.

D. Based upon our criteria and assessment of the peer-reviewed literature, electrical bone growth stimulation has not been demonstrated to improve patient outcomes in the treatment of **fresh fractures, stress fractures, delayed unions, or fresh bunionectomies** and, therefore, is considered **investigational**.

E. Based upon our criteria and assessment of the peer reviewed literature, **invasive and noninvasive** electrical stimulation is considered **investigational** for **ALL** of the following indications:
   1. acute or chronic lumbar spondylolysis (pars interarticularis defect) with or without spondylolisthesis;
   2. failed cervical or lumbar disc arthroplasty;
   3. spinal malignancy;
   4. as nonsurgical treatment of an established pseudarthrosis.

F. Based upon our criteria and assessment of the peer reviewed literature, **semi-invasive** electrical bone growth stimulation is considered **investigational** for any indication due to lack of sufficient evidence of its effectiveness.

G. **Contraindications** of the use of electrical bone growth stimulation include:
   1. Fracture gaps greater than one centimeter; and
   2. Presence of a demand-type pacemaker or an implantable cardioverter defibrillator.

II. ULTRASONIC BONE GROWTH STIMULATION

A. Based upon our criteria and assessment of the peer-reviewed literature, ultrasound accelerated fracture healing systems have been medically proven to be effective when used to treat non-union fractures (excluding fractures of the skull or vertebrae and tumor-related fractures) and, therefore, are considered **medically appropriate** when **ALL** of the following criteria are met:
   1. At least (3) three months have elapsed since injury;
   2. Nonunion of the fracture is documented by a minimum of (2) two sets of radiographs obtained prior to starting treatment with the ultrasonic (US) device, separated by a minimum of 90 days, each including multiple views of the fracture site, and with written interpretation by a physician stating that there has been no clinically significant evidence of fracture healing between the two sets of radiographs.

B. Based upon our criteria and assessment of the peer-reviewed literature, ultrasound accelerated fracture healing systems do not significantly improve patient outcomes and, therefore, are considered **not medically necessary** for **ANY** of the following indications:
   1. To accelerate healing of fresh, closed, posteriorly displaced distal radius fractures;
   2. To accelerate healing of fresh, closed or Grade 1 tibial diaphysis fractures;
   3. To accelerate healing of fresh fractures, fusions, or delayed unions of the scaphoid (carpal navicular);

4. To treat delayed union of fractures;
5. To treat congenital pseudoarthrosis;
6. To treat Charcot arthropathy (except that treatment of fractures related to Charcot arthropathy using ultrasonic bone growth stimulators are considered medically necessary when all of the criteria listed in II.A. are met);
7. To treat osteogenesis imperfecta.

III. Repair and/or replacement of a medically necessary bone growth stimulators and/or components not under warranty will be considered **medically appropriate** when the following criteria are met:

A. Physician documentation includes **ALL** of the following:

1. date of device implantation/initiation,
2. manufacturer warranty information, and
3. attestation that the patient has been compliant with the use of device and will continue to benefit from the use of device;

AND ONE OF THE FOLLOWING APPLY:

B. Repair of the currently used device, when **ALL** of the following are met:

1. it is no longer functioning adequately;
2. inadequate function interferes with activities of daily living;
3. repair is expected to make the equipment fully functional (as defined by manufacturer); **or**

C. Replacement of the currently used device, when the following are met:

1. it is no longer functioning adequately;

AND EITHER

2. has been determined to be non-repairable; **or**
3. the cost of the repair is in excess of the replacement cost; **or**

D. Replacement of the currently used device, when **BOTH** of the following are met:

1. there is documentation that a change in the patient's condition makes the present unit non-functional; **and**
2. improvement is expected with a replacement unit.

IV. Repair or replacement of equipment damaged due to patient neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.

V. The replacement of properly functioning bone growth stimulators and/or external components is considered **not medically necessary**. This includes, but is not limited to, replacement desired due to advanced technology or in order to make the device more aesthetically pleasing.

Refer to Corporate Medical Policy #2.01.31 Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal Conditions and Soft Tissue Wounds

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services

POLICY GUIDELINES

I. Prior authorization is contract dependent.

II. Ultrasound accelerated healing devices are not to be used in conjunction with any other noninvasive osteogenic stimulation device.

DESCRIPTION

Electrical Bone Growth Stimulators

Electrical bone growth stimulators are used to induce the growth of bones in cases of delayed union or non-union of fractures.

I. Noninvasive stimulators use an external power supply and externally applied coils that produce an electrical current to the fracture site via pulsed electromagnetic fields (PEMFs), combined electromagnetic field (CEMF)

technology, or capacitive coupling to stimulate bone growth. Direct electrical current has been shown to have a stimulatory effect on bone formation. The bulk of the scientific evidence demonstrating the efficacy of noninvasive electrical bone growth stimulation addresses its use for nonunion fractures in long bones or as an adjunct to lumbar or lumbosacral spinal fusion.

II. Invasive stimulators use a current generator that is surgically implanted in an intramuscular subcutaneous space and connected to an electrode that is implanted within the bone fragments that are hoped to be fused. The power source is removed in a second surgical procedure once it has discharged.

Ultrasonic Bone Growth Stimulators

Ultrasonic bone growth stimulators are noninvasive devices that emit low intensity pulsed ultrasound to accelerate bone repair over the fracture site on the skin. Sonic accelerated fracture healing system (SAFHS), is a noninvasive device that uses low intensity, pulsed, ultrasound therapy to stimulate and accelerate fracture healing time of the tibial diaphysis. The device consists of two main components: a signal generator about the size of a laptop computer and a small, square transducer connected to the generator by cable. The transducer is applied to the skin over the fracture site using a gel to facilitate transmission of the ultrasound signal. In 2022, the FDA approved the AccelStim bone growth stimulator. This device delivers a high frequency sound wave similar to the EXOGEN bone healing system, to encourage bone growth and help heal bones fractures of the larger bone between the elbow and wrist (radius) or the larger long bone in the lower leg (tibia) heal faster. It is indicated for use in adults.

Delayed Unions

Defined by using clinical and radiographic findings suggesting an un-united fracture where the possibility of healing exists and there are no indications that union will fail. Healing has not advanced at the "average" rate for the location and type of fracture.

Non-Unions

Defined by radiographic findings with clinical mobility of the bone fragments, where bone healing has ceased, more than three months have elapsed since the fracture occurred and there are no longer any visible signs that union will occur.

Failed Spinal Fusion

Defined as a spinal fusion that has not healed at a minimum of six months after the original surgery, as evidenced by serial X-rays over three months.

The Meyerding Classification

The Meyerding classification describes the degree of translation of spondylolisthesis. The grade is determined by measuring the degree of slip using standing, neutral lateral radiographs of the lumbar spine.

A. The classification system divides slip into five grades:
    1. Grade I: 0% to 25%
    2. Grade II: 25% to 50%
    3. Grade III: 50% to 75%
    4. Grade IV: 75% to 100%
    5. Grade V: greater than 100% (Koslosky and Gendelberg, 2020).

RATIONALE

The United States Food and Drug Administration (FDA) has granted premarket approval for the Biomet EBI Bone Healing System, the Orthologic Bone Growth Stimulator, the Orthofix Physio-Stim Life, the OrthoPak Bone Growth Stimulator Systems, and the Zimmer Biomet Osteogen, Zimmer Biomet Direct Current Bone Growth Stimulator.

There is sufficient evidence reported in the peer-reviewed literature to conclude that external electrical stimulation improves outcomes for non-union of fractures, for infantile non-union, for failed joint fusion, and for non-surgical salvage for pseudoarthrosis. Noninvasive and invasive electrical bone stimulation improves outcomes when used as an adjunct to spinal fusion surgery for patients at high risk for pseudoarthrosis. Improved outcomes have been achieved outside the

investigational setting. A randomized, controlled trial (RCT) to determine whether interferential current could significantly reduce healing time in new fractures of the tibia or prevent non-union found no significant difference in time to union, compared to placebo. An RCT to determine whether interferential current would accelerate tibial stress fracture healing found no difference in time to healing between treatment and placebo groups. Greater device use and less weightbearing load enhanced the effectiveness of the active device. A 2002 meta-analysis of trials of the effect of electrical stimulation on musculoskeletal systems included four studies of fresh fractures, all of them failing to provide evidence of efficacy.

FDA premarket approval was granted to the Exogen 2000 SAFHS in 1994 for treatment of fresh Colles fractures and open tibial diaphysis fractures when managed by closed reduction and casting, and approval was expanded to non-unions in 2000. Data presented to the FDA as part of the approval process for the SAFHS device demonstrated that, in 64 of 74 cases, non-unions (mean fracture age nearly three years) were healed with use of low-intensity ultrasound. Patients receiving drugs that alter bone metabolism were excluded from studies of the device. Two studies of ultrasound after intramedullary nailing and fixation with absorbable screws showed no benefit from ultrasound. Most fresh fractures heal following standard care, such as closed reduction and casting. The United Kingdom's National Institute for Health and Clinical Excellence (NICE) updated its guidance on low-intensity pulsed ultrasound for the treatment of nonunion and delayed fracture healing in 2013. NICE reached the following conclusions: Clinical evidence shows a high rate of fracture healing that supports the use of the EXOGEN ultrasound bone healing system to treat long-bone fractures with nonunion (failure to heal after nine months). In addition, the EXOGEN ultrasound bone healing system to treat long-bone fractures with nonunion is associated with an estimated cost saving when compared with current management, through the avoidance of surgery. There is some radiological evidence of improved healing when the EXOGEN ultrasound bone healing system is used for long-bone fractures with delayed healing (no radiological evidence of healing after approximately three months). There are substantial uncertainties about the rate at which bone healing progresses without adjunctive treatment between three and nine months after fracture, and about whether or not surgery would be necessary. These uncertainties result in a range of cost consequences, some cost-saving and others that are more costly than current management.

RCTs evaluating the use of low-intensity pulsed ultrasound following fresh fracture reported no statistically significant differences in radiographic healing, physical component score of the SF-36, use of physical therapy, need for secondary procedures, use of nonsteroidal anti-inflammatory drugs, and time to first visible callus. No studies were identified that included children younger than age 17 years. The mechanism for the effect of ultrasound on bone healing is not fully understood.

The American Academy of Orthopedic Surgeons (AAOS) publishes information on non-unions, which occur when a broken bone fails to heal and "delayed unions," which occur when a fracture takes longer than usual to heal. Some broken bones do not heal even when they get the best surgical or nonsurgical treatment, because of inadequate stability, limited blood supply, or lack of good nutrition to promote healing. Some bones can be expected to heal with minimal treatment due to inherent stability and excellent blood supply (toe bones). Other bones may not heal as quickly due to a limited blood supply (femoral head and neck, small wrist bone (scaphoid). Bones with moderate blood supply (tibia) may not heal quickly because the skin and muscle over the bone were damaged, and the external blood supply was impaired. In addition, certain risk factors make it more likely that a bone will fail to heal. These risk factors include tobacco or nicotine use in any form, older age, severe anemia, diabetes, hypothyroidism, infection, certain medications, and low vitamin D level.

The FDA has given Section 501(k) premarket approval for the SpinalPak, Spinal-Stim Lite, Physio-Stim Life, and SpinaLogic external stimulators and the SpF implanted spinal fusion stimulators.

For individuals who are at high risk of lumbar spinal fusion failure surgery and who receive invasive or noninvasive electrical bone growth stimulation, the evidence includes systematic reviews and RCTs. Relevant outcomes are symptoms, change in disease status, and functional outcomes. Results from these trials have indicated that, in patients with risk factors for failed fusion, either invasive or noninvasive electrical bone stimulation increases the fusion rate. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have failed lumbar spinal fusion surgery and who receive noninvasive electrical bone growth stimulation, data has shown that noninvasive electrical stimulation improves fusion rates in this population. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Foley et al. published results of the investigational device exemption study of pulsed electromagnetic field (PEMF) stimulation (Cervical-Stim device from Orthofix) as an adjunct to anterior cervical discectomy and fusion (ACDF) with anterior cervical plates and allograft interbody implants. A total of 323 patients were randomized, 163 to PEMF and 160 to no stimulation. All patients were active smokers (159 of whom smoked more than one pack of cigarettes per day) or were undergoing multilevel ACDF (192 patients). The patients in the treatment group wore the Cervical-Stim device for four hours per day for three months starting one week after surgery. Efficacy was measured by radiographic analysis at months 1, 2, 3, 6, and 12. Fusion rates for the 240 evaluable patients at six months were 83.6% for the PEMF group and 68.6% for the control group (p=.0065). By intent-to-treat analysis, assuming that non-evaluable patients did not have fusion, PEMF and control groups fusion rates were 65.6% and 56.3%, respectively (p=.0835). Of 245 patients available for follow-up at 12 months, fusion was achieved in116 of 125 PEMF patients and 104 of 120 control patients (p=.1129). Patient compliance, which was automatically monitored by the device, was assessed at each visit; however, compliance data were not included in the paper. The large number of dropouts, non-significant difference in fusion rates by intent-to-treat analysis, and lack of data on functional outcomes (e.g., pain, return to usual activity) limit interpretation of these study results. Thus, this technique is considered investigational for the cervical spine.

In 2016, the North American Spine Society (NASS) issued a coverage recommendation for electrical bone growth stimulators. The recommendation includes coverage for augmentation of spinal fusion in any and all regions of the spine of two or more motion segments (three vertebrae), even though there is less support for areas other than the lumbar spine and in patients who have co-morbidities that may put them at risk for delayed bone healing (e.g., smoking history, diabetes, immunocompromised). However, the rationale section included in the recommendations did not mentions any level of evidence or any specific referenced articles.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not Medically Necessary = (NMN).*

CPT Codes

Code	Description
20974	Electrical stimulation to aid bone healing; noninvasive (non-operative)
20975	Electrical stimulation to aid bone healing; invasive (operative)
20979	Low intensity ultrasound stimulation to aid bone healing, noninvasive (nonoperative)

HCPCS Codes

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, noninvasive

ICD10 Codes

Code	Description
M43.22-M43.23	Fusion of spine, cervical region, cervicothoracic region (code range)
M43.27-M43.28	Fusion of spine, lumbosacral, sacral and sacrococcygeal region (code range)
M51.04-M51.9	Thoracic, thoracolumbar, and lumbosacral intervertebral disc disorders (code range)
M53.2x7-M53.2x8	Spinal instabilities, lumbosacral, sacral and sacrococcygeal region (code range)
M53.3	Sacrococcygeal disorders, not elsewhere classified
M53.86-M53.88	Other specified dorsopathies, lumbosacral, sacral and sacrococcygeal region (code range)
M80.00XK	Age-related osteoporosis with current pathological fracture, unspecified site, subsequent encounter for fracture with nonunion
M80.021K-M80.879K	Osteoporosis with current pathological fracture, subsequent encounter for fracture with nonunion (code range)
M84.40xK	Pathological fracture, unspecified site, subsequent encounter for fracture with nonunion
M84.421K-M84.48XK	Pathological fracture, subsequent encounter for fracture with nonunion (code range)
M84.68XK	Pathological fracture in other disease, other site, subsequent encounter for fracture with nonunion
Q68.8	Other specified congenital musculoskeletal deformities
Q71.61-Q71.63	Lobster-claw hand (code range)
Q74.0-Q74.9	Other congenital malformations of limb(s) (code range)
S42.001K-S42.92XK	Fracture of shoulder and upper arm, subsequent encounter for fracture with nonunion (code range)
S49.001K-S49.199K	Other and unspecified fracture of shoulder and upper arm, subsequent encounter for fracture with nonunion (code range)
S52.001K-S52.92XN	Fracture of ulna and forearm, subsequent encounter for closed fracture with nonunion, subsequent encounter for open fracture type I or II with nonunion, subsequent encounter for open fracture type IIIA, IIIB, or IIIC with nonunion (code range)
S59.001K-S59.299K	Other and unspecified fracture of elbow and forearm, subsequent encounter for fracture with nonunion (code range)
S72.001K-S72.92XN	Fracture of femur, subsequent encounter for closed fracture with nonunion, subsequent encounter for open fracture type I or II with nonunion, subsequent encounter for open fracture type IIIA, IIIB, or IIIC with nonunion (code range)
S79.001K-S79.199K	Other and unspecified fracture of hip and thigh, subsequent encounter for fracture with nonunion (code range)

Code	Description
S82.101K-S82.92xN	Fracture of lower leg, including ankle, subsequent encounter for closed fracture with nonunion, subsequent encounter for open fracture type I or II with nonunion, subsequent encounter for open fracture type IIIA, IIIB, or IIIC with nonunion (code range)
S89.001K S89.399K	Other and unspecified fracture of lower leg, subsequent encounter for fracture with nonunion (code range)
S92.201K-S92.919K	Fracture of foot and toe, except ankle, subsequent encounter for fracture with nonunion (code range)

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*Key Article

KEY WORDS

Bone Growth Stimulator, Osteogenic Stimulator, SAFHS, Ultrasonic Bone Growth Stimulator, US, Low Intensity Pulsed Ultrasound Fracture Healing, Pulsed ElectroMagnetic Field (PEMF), Capacitively Coupled Electric Field (CCEF).

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) 150.2 for Osteogenic Stimulators. Please refer to the following NCD website for Medicare Members: [http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=65&ncdver=2&bc=BAABAAAAAAAA&] accessed 03/01/24.

There is currently a Local Coverage Determination (LCD) L33796 for Osteogenesis Stimulators. Please refer to the following LCD website for Medicare Members: [https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33796&ContrID=140] accessed 03/04/24.