MEDICAL POLICY

Medical Policy Title	**Bone Growth Stimulators**
Policy Number	**1.01.53**
Current Effective Date	**April 16, 2026**
Next Review Date	**April 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service.
(Link to Product Disclaimer)

POLICY STATEMENT(S)

Electrical Bone Growth Stimulation

I. Noninvasive electrical bone growth stimulation is considered **medically appropriate** for **ANY** of the following indications:

   A. Infantile non-union;

   B. Failed joint fusion of the ankle or knee;

   C. The treatment is for non-union secondary to trauma of the bones of the appendicular skeleton (e.g., humerus, ulna, radius, carpals, metacarpals, femur, tibia, fibula, tarsals, metatarsals, phalanges, scapula, clavicle, pelvis, and patella) when **ALL** of the following criteria are met:

      1. Three (3) months or more have elapsed since the injury or initial treatment;

      2. The individual has been adequately immobilized to establish a stable mechanical environment that supports normal biologic fracture healing, and when appropriate, is likely to comply with non-weight bearing.

      3. Non-union must be documented by at least two (2) sets of serial radiographs of the fracture or fusion site, obtained a minimum of 90 days apart, demonstrating no clinically significant progression of healing; **and**

      4. The fracture gap is 1 centimeter or less;

   D. Treatment for individuals with failed spinal fusion when **BOTH** of the following criteria are met:

      1. A minimum of six (6) 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 (3) months during the latter portion of the six (6) month post-fusion surgery period.

   E. Invasive (inserted at the time of surgery) or noninvasive (beginning at any time from the time of surgery until up to six (6) months after surgery) electrical bone growth stimulation is

considered **medically appropriate** for spinal fusion surgery when:

1. Individuals are at high risk with **ANY** of the following risk factors for fusion failure:
    a. One (1) or more previous failed spinal fusions;
    b. Multi-level fusion involving three (3) or more vertebrae (e.g., two vertebral interspaces);
    c. Meyerding Grade III or worse lumbar/lumbosacral spondylolisthesis;
    d. Smoking history;
    e. Alcohol use disorder;
    f. Diabetes, renal disease, or other metabolic diseases when bone healing is likely to be compromised;
    g. Nutritional deficiency/malnutrition;
    h. Osteoporosis defined as a T-score of less than -2.5 on a recent (within one year) DEXA;
    i. Body Mass Index (BMI) greater than 30;
    j. Severe anemia;
    k. Glucocorticoid dependency; **or**
    l. Immunocompromised status.

II. Electrical bone growth stimulation is considered **investigational** for **ANY** of the following indications:
    A. Fresh fractures;
    B. Stress fractures;
    C. Delayed unions;
    D. Fresh bunionectomies.

III. Invasive and noninvasive electrical stimulation is considered **investigational** for **ALL** of the following indications:
    A. Acute or chronic lumbar spondylolysis (pars interarticularis defect) with or without spondylolisthesis;
    B. Failed cervical or lumbar disc arthroplasty;
    C. Spinal malignancy;
    D. As nonsurgical treatment of established pseudarthrosis.

IV. Semi-invasive electrical bone growth stimulation is considered **investigational** for any indication.

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

Ultrasonic Bone Growth Stimulation

V. Ultrasound accelerated fracture healing systems, when used to treat non-union fractures (excluding fractures of the skull or vertebrae and tumor-related fractures), are considered **medically appropriate** when **ALL** of the following criteria are met:
    A. At least (3) three months have elapsed since injury;
    B. 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**
    C. Written interpretation by a physician stating that there has been no clinically significant evidence of fracture healing between the two sets of radiographs.

VI. Ultrasound accelerated fracture healing systems are considered **not medically necessary** for **ANY** of the following indications:
    A. To accelerate healing of fresh, closed, posteriorly displaced distal radius fractures;
    B. To accelerate healing of fresh, closed or Grade 1 tibial diaphysis fractures;
    C. To accelerate healing of fresh fractures, fusions, or delayed unions of the scaphoid (carpal navicular);
    D. To treat delayed union of fractures;
    E. To treat congenital pseudoarthrosis;
    F. 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);
    G. To treat osteogenesis imperfecta.

Bone Growth Stimulator Repair

V. Repair of a medically necessary bone growth stimulators or components not under warranty will be considered medically appropriate when the following criteria are met:
    A. Physician documentation includes **ALL** the following:
        1. Date of bone growth stimulator initiation/implantation;
        2. Manufacturer warranty information, if applicable;
        3. Attestation that the patient has been compliant with the use of the bone growth stimulator and will continue to benefit from the use of the bone growth stimulator;
    B. The device is no longer functioning adequately; and **BOTH** of the following criteria are met:

1. Inadequate function interferes with activities of daily living; **and**
2. Repair is expected to make the equipment fully functional (as defined by manufacturer).

VI. Repair 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**.

Bone Growth Stimulator Replacement

VII. Replacement of a medically necessary bone growth stimulator or components not under warranty will be considered **medically appropriate** when **EITHER** of the following criteria are met:

A. The bone growth stimulator is no longer functioning adequately and has been determined to be non-repairable or the cost of the repair is in excess of the replacement cost; or

B. There is documentation that a change in the patient's condition makes the present unit non-functional and improvement is expected with a replacement unit.

VIII. The replacement of a properly functioning bone growth stimulator, its components or accessories is considered **not medically necessary**. This includes, but is not limited to, replacement desired due to advanced technology or to make the bone growth stimulator more aesthetically pleasing.

IX. The replacement of equipment damaged or lost 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**.

X. Accessories or components for a bone growth stimulator that is considered not medically necessary or investigational by peer-reviewed literature will also be considered as **not medically necessary or investigational** by the Health Plan.

RELATED POLICIES

Corporate Medical Policy

1.01.55 Electrical Stimulation as a Treatment for Pain and Other Medical Conditions

2.01.31 Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal Conditions and Soft Tissue Wounds

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

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

DESCRIPTION

Standard fracture care involves reducing the fracture when needed and then immobilizing or fixing the bone so that the fracture site is mechanically stable. Immobilization is essential because it limits abnormal movement, maintains proper alignment, and establish a stable mechanical environment that supports normal biologic fracture healing. When the fracture is adequately stabilized, healing can occur either directly or through callus formation, depending on the type of fracture and the fixation used. Without enough immobilization or fixation, too much movement at the fracture site disrupts healing and can prevent the bone from uniting. Therefore, it is not reasonable to expect a fracture to heal if it is not immobilized or fixed well enough to control abnormal motion at the site.

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 typically implanted in the gluteal region and connected to an electrode that is implanted within the bone fragments that are intended for fusion. 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.

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 Meyerding classification may be instrumental for tracking prior progression of displacement and assisting in the evaluation of the other factors. The grade is determined by measuring the degree of slip using standing, neutral lateral radiographs of the lumbar spine.

I. The classification system divides slip into five grades:
   A. Grade I: 0% to 25%
   B. Grade II: 25% to 50%
   C. Grade III: 50% to 75%
   D. Grade IV: 75% to 100%
   E. Grade V: greater than 100%

SUPPORTIVE LITERATURE

The U.S. Food and Drug Administration (FDA) approval of electrical bone growth stimulators as a treatment of nonunion fractures involving the appendicular skeleton were based on a number of case series in which individuals with nonunion fractures, primarily of the tibia, served as their control group (Connelly 1984). These studies from the 1980s have suggested that electrical stimulation resulted in subsequent unions in a significant percentage of individuals.

Simonis et al (2003) compared pulsed electromagnetic field stimulation with placebo treatment for tibial shaft fractures ununited at least one year after fracture, with no metal implant bridging the fracture gap and no radiographic progression of healing in the three (3) months before treatment. A total of 34 individuals received surgical treatment with osteotomy and unilateral external fixator before randomization. Treatment was delivered by external coils and control subjects received sham treatment using identical machines not passing current through the coils. Individuals were assessed monthly for six months, and clinical radiographic assessments were conducted. If union was not achieved at six months, then treatment was considered a failure. In the treatment group, 89% (16/18) of fractures healed compared with 50% (8/16) in the control group (p=.02). There was an imbalance in smoking habits between groups. The union rate in the subgroup that smoked was 75% (6/8) in the treatment group, compared to 46% (6/13) in the control group. The treatment group of nonsmokers had 100% union rate compared to 67% in the control group. There were a larger percentage of smokers in the treatment group healed compared with those in the control group. Overall, 24 out of the 34 individuals progressed to union. The authors concluded the available evidence supported the use of pulsed electromagnetic field therapy in the treatment of nonunion of the tibia and suggested that future trials consider which electromagnetic stimulation modality and for which anatomic sites the treatment is most effective.

Foley and colleagues (2008) 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 in 116 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.

Searle et al 2023 assessed the effects of low-intensity ultrasound (LIPUS), high-intensity focused ultrasound (HIFU) and extracorporeal shockwave therapies (ECSW) as part of the treatment of acute fractures in adults. Randomized controlled trials (RCTs) and quasi-RCTs including participants over 18 years of age with acute fractures (complete or stress fractures) treated with either LIPUS, HIFU or ECSW versus a control or placebo-control were included. There were 21 studies, involving 1543 fractures in 1517 participants. There were two studies that were quasi-RCTs, 20 studies that evaluated LIPUS, and one trial evaluated ECSW. None of the studies evaluated HIFU. There were four studies that did not report any of the critical outcomes. All studies had unclear or high risk of bias in at least one domain. The certainty of the evidence was downgraded for imprecision, risk of bias and inconsistency. The researchers were uncertain of the effectiveness of ultrasound and shock wave therapy for acute fractures in terms of patient-reported outcome measures (PROMS), for which few studies reported data. Researchers concluded that it was probable that LIPUS makes little or no difference to delayed union or non-union fractures.

PROFESSIONAL GUIDELINE(S)

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 mention any level of evidence or any specific referenced articles.

The National Institute for Health and Care Excellence (NICE) 2018 recommendation did not show efficacy of low intensity pulsed ultrasound to promote healing fresh fractures at low risk of non-healing and recommended the procedure should not be used for this indication.

In 2019 NICE updated its guidance on low-intensity pulsed ultrasound for the treatment of nonunion and delayed fracture. The case for adopting the EXOGEN ultrasound bone healing system to treat long bone fractures with non-union (failure to heal after 9 months) were supported by the clinical evidence that showed high rates of fracture healing. The EXOGEN ultrasound bone healing system to treat long bone fractures with non-union was associated with an estimated cost savings of approximately $2,500 per individual compared with current management, through avoiding surgery. According to NICE, EXOGEN ultrasound bone healing system when used for long bone fractures with delayed healing (no radiological evidence of healing after approximately 3 months) showed some radiological evidence of improved healing. There were substantial uncertainties about the rate at which bone healing progresses without adjunctive treatment between 3 and 9 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.

In 2022, the American Academy of Orthopedic Surgeons (AAOS) published guidelines on the treatment of clavicle fractures. The guideline included a moderately strong recommendation that low-intensity pulsed ultrasound should not be used for acute mid shaft clavicle fractures. This recommendation was based on a lack of data supporting its efficacy for accelerated healing or improved non-union rates.

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) regulates bone growth stimulators as medical devices. All bone growth stimulators including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 Mar 18]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: Medical Device Recalls | FDA [accessed 2026 Mar 18]

Device Approvals

In 1984, the noninvasive OrthoPak Bone Growth Stimulator (BioElectron, now Zimmer Biomet) was approved by the FDA through the premarket approval process for treatment of fracture nonunion.

Pulsed electromagnetic field systems that had obtained FDA premarket approval (all noninvasive devices) include Physio-Stim (Orthofix), first approved in 1986, and OrthoLogic 1000, approved in 1997, both indicated for the treatment of established nonunion secondary to trauma, excluding vertebrae and all flat bones, in which the width of the nonunion defect is less than one-half the width of the bone to be treated. The EBI Bone Healing System (Electrobiology, now Zimmer Biomet), which was first approved in 1979 and indicated for nonunions, failed fusions, and congenital pseudarthrosis. No distinction was made between long and short bones.

SpinalPak, Spinal-Stim Lite, Physio-Stim Life, and SpinaLogic external stimulators and the SpF implanted spinal fusion stimulators were given Section 501(k) premarket FDA approval in 1999.

The FDA granted premarket approval of Exogen 2000+ Sonic Accelerated Fracture Healing System

(SAFHS) (now known as Exogen Ultrasound Bone Healing System; Bioventus) in 1994 as a treatment device for the acceleration of fresh fracture healing.

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.

Currently, there are no semi-invasive electrical bone growth stimulator devices with FDA approval or clearance.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

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)

Code	Description
M43.26-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)

Code	Description
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)
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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SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Osteogenic Stimulators (NCD 150.2) [accessed 2026 Mar 19]

Osteogenesis Stimulators (LCD L33796) [accessed 2026 Mar 19]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, 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 HISTORY/REVISION

Committee Approval Dates

10/18/01, 02/21/02, 01/16/03, 02/19/04, 02/24/05, 02/23/06, 12/07/06, 10/24/07, 08/28/08, 10/28/09, 04/28/11, 04/26/12, 06/28/12, 04/25/13, 04/24/14, 04/23/15, 06/22/16, 06/22/17, 04/26/18, 02/28/19, 02/27/20, 02/25/21, 04/22/21, 04/21/22, 04/20/23, 04/18/24, 04/17/25, 04/16/26

Date	Summary of Changes
04/16/26	• Annual review; formatting update with clarification of policy statement addressing the timing requirement for radiographs. Policy intent unchanged.
04/17/25	• Annual review; Policy intent unchanged.
01/01/25	• Summary of changes tracking implemented.
10/18/01	• Original effective date