

Electrical and Ultrasound Bone Growth Stimulators (for Tennessee Only)

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[Instructions for Use](#)

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Commercial Policy
• Electrical and Ultrasound Bone Growth Stimulators

Application

This Medical Policy applies to Medicaid only plans in the state of Tennessee.

Coverage Rationale

The use of invasive or noninvasive spinal electrical bone growth stimulator is considered proven and medically necessary as an adjunct to lumbar spinal fusion surgery for individuals with radiographic evidence of skeletal maturity for any of the following indications associated with an increased risk for fusion failure:

- Previously failed fusion at the same site, when minimum of six months has elapsed since the last surgical procedure
- Spinal fusion performed or to be performed at more than one level as part of a single surgery
- Comorbid conditions associated with compromised bone healing (e.g, diabetes, obesity, osteoporosis, current tobacco use)
- Spondylolisthesis grade II or greater

The use of invasive or noninvasive spinal electrical bone growth stimulators is unproven and not medically necessary for the treatment of all other indications due to insufficient evidence of efficacy and/or safety.

The use of ultrasonic bone growth stimulators is proven and medically necessary for the treatment of nonunion of long bone fractures when all of the following criteria are met:

- Fracture gap is less than or equal to 1 cm
- Radiographic evidence shows ≥ three months persistence of the fracture line without bridging callus
- Fracture reduced and immobilized
- Less than 6 months have passed since the date of most recent surgical operation
- Fracture that is not pathological or associated with malignancy
- Radiographic evidence of skeletal maturity

The use of ultrasonic bone growth stimulators is unproven and not medically necessary for the treatment of all other indications due to insufficient evidence of efficacy and/or safety.

Definitions

Delayed Union: A fracture has not healed within the expected time period. The fact that a bone is delayed in its union does not mean that it will become a non-union.

Electrical Bone Growth Stimulation: The use of a device (either implanted into the body or worn externally), that uses an electric field or current to stimulate the growth of bone tissue.

- Invasive: The implantable current generator is surgically placed in an intramuscular or subcutaneous space, while an electrode is implanted within the fragments of bone graft at the targeted fusion site. The implanted device is usually functional for 6 to 9 months at which point the current generator is removed in a second surgical procedure, while the electrodes may or may not be removed. Implantable bone growth stimulators are used as an adjunct to spinal fusion surgery and implanted at the time of surgery.
- Non-Invasive: An external power source generates a weak electrical current to the target sites using either pulsed electromagnetic fields, capacitive coupling or combined magnetic fields.

Fracture Union: The point at which the fractured bone has regained sufficient strength and stiffness to function as a weightbearing structure without external support.

Non-Union Fracture: The result of an arrest in the healing process and is defined by the following three findings:

- Motion at the fracture site
- Radiographic evidence showing the persistence of the fracture line without bridging callus
- Incomplete progression toward radiographic healing in the expected length of time for the given bone and further healing not expected

Ultrasonic Bone Growth Stimulation: The use of a non-invasive device that emits low intensity, pulsed ultrasound to accelerate bone repair. The device is characterized by a main operating unit with an external power supply that is connected to a treatment head module affixed to a mounting fixture, and centered over the fracture site. This device is specifically programmed to promote accelerated fracture healing.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
Electrical Bone Growth Stimulator: Non-Spinal (Invasive, Non-Invasive)	
20974	Electrical stimulation to aid bone healing; noninvasive (nonoperative)
20975	Electrical stimulation to aid bone healing; invasive (operative)
Ultrasound Bone Growth Stimulator	
20979	Low intensity ultrasound stimulation to aid bone healing, noninvasive (nonoperative)

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Coding Clarification: Utilize HCPCS code E0748 when reporting bone growth stimulation for all anatomical levels of the spine.

HCPCS 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, non-invasive

Description of Services

Bone healing is a complex process dependent on a variety of factors. The rate of bone repair and composition of tissue varies depending on type of bone fractured, the extent of the bone and soft tissue damage, the adequacy of the blood supply, and the degree of separation between bone ends. The individual's general health and nutritional status also play a significant role in bone healing. The presence of infection may adversely affect healing. Diminished blood flow to the fracture site will often suppress the healing response; factors that can cause diminished blood flow include heavy smoking, malnutrition, diabetes, alcoholism, peripheral vascular disease, increasing age, and the use of some medications such as steroids. Other characteristics such as high-grade trauma, high grade and open fractures, comminution of the fracture, vertical or oblique fracture pattern, and fracture displacement may also contribute to poor healing of bone (Agency for Healthcare Research and Quality [AHRQ], 2005).

Bone growth stimulation is utilized to promote bone healing in difficult to heal fractures or fusions by applying electrical or ultrasonic current to the fracture/fusion site. Ultrasonic stimulation is applied externally, while electrical stimulation can be applied either from the outside of the body (noninvasive) or from the inside of the body (invasive).

Bone growth stimulators are only indicated for use in individuals who are skeletally mature. A person is said to be skeletally mature when all bone growth is complete; the cartilage cells of the growth plate cease to proliferate, the growth plate becomes thinner, is replaced by bone and disappears, and the epiphysis is "closed" or fused with the shaft.

Clinical Evidence

Electrical Bone-Growth Stimulators

A Hayes Medical Directory Technology (Hayes, 2016) report analyzed the evidence for invasive electrical bone growth stimulation for treatment of delayed fracture, fracture nonunion and for individuals undergoing arthrodesis. A total of 11 trials were included in the assessment, three RCTs, three comparative, and five uncontrolled case series. Sample populations ranged from 10-143 per study, with five of the trials limited in scope to lumbar arthrodesis, one to cervical arthrodesis, two to foot/ankle arthrodesis, and three to delayed or nonunion fracture treatment. Follow-up evaluations ranged from six months to 10 years. Hayes concluded there is mixed, low-quality evidence evaluating effectiveness of invasive electrical stimulation used as an adjunct to lumbar spinal arthrodesis. According to the report some of the evidence is older and suggests that invasive electrical stimulation as an adjunct to lumbar spinal arthrodesis may offer benefit to patients at high risk for pseudarthrosis. However, findings from the available RCTs were conflicting, with 1 older RCT suggesting improved fusion rates with use and 2 newer, better-quality RCTs suggesting no benefit. The quality of evidence was of very low quality for all other indications, such as arthrodesis of the cervical spine, arthrodesis of foot and ankle, delayed union or nonunion fracture. Specifically, for cervical spine fusion, the authors identified only on very low-quality case series without comparison group. The authors concluded that, overall, the technology appears generally safe; with no serious or severe complications being attributable to the device used. Updated reviews published by Hayes since the initial report indicate there has been no change to the evidence.

Shi et al (2013) reported a randomized sham-controlled trial that included 58 patients with delayed union of surgically-reduced long-bone fractures (femur, tibia, humerus, radius or ulna). 12 Delayed union was defined as a failure to heal after at least 16 weeks and not more than 9 months following surgical reduction and fixation of the fracture. Patients with fracture nonunion, defined as failure to heal after more than 9 months, were excluded from the study. Treatment with 8 hours of pulsed electromagnetic field therapy (PEMF) per day was stopped when no radiographic progression was observed over 3 months or when union was achieved, with union defined as no pain during joint stressing or during motion at the fracture site and callus bridging for 3 out of 4 cortices on blinded assessment. Three months of treatment resulted in a slight, but not statistically

significant, improvement in the rate of union between PEMF-treated patients and controls (38.7% vs. 22.2%). The success rate was significantly greater with PEMF (77.4% vs. 48.1%) after an average of 4.8 months of treatment. The time to union was not significantly different between PEMF (4.8 months; range, 2-12) and sham controls (4.4 months; range, 2-7).

A systematic review of electrical stimulation to enhance bone healing by Griffin identified 105 clinical studies and 35 in vitro studies of the technology. Direct current was found to be effective in enhancing bone healing in spinal fusion, as supported by four studies at level of evidence 1 (randomized control trial). The authors found support for its use for nonunion fractures, but only based on level of evidence 4 (case series). Eleven studies were retrieved for capacitive coupling suggesting its effectiveness for spinal fusion but, for treating nonunions, the findings were conflicting. Studies of inductive coupling for long bones had conflicting findings. Overall, the studies, although in favor of electrical stimulation application in bone repair, displayed variability in treatment regime, primary outcome measures, follow-up times, and study design, making critical evaluation and assessment difficult (Griffin, 2011).

A randomized controlled trial by Foley, et al (2008) tested the efficacy of PEMF stimulation to support cervical fusion in 323 participants with compressed cervical nerve root and symptomatic radiculopathy appropriate to the compressed root that had failed to respond to nonoperative management. While the group randomized to PEMF showed a significantly higher fusion rate than the control group (83.6% vs. 68.6%, $p=0.0065$) at six months, the group difference disappeared at 12 months post-surgery (92.8% vs. 86.7%, $p=0.1129$). Additionally, the study failed to show any group difference in patient-centered outcome such as pain scores, neck disability index, or functional status at 6 or 12 months. The authors concluded that although PEMF stimulation appeared to hasten bone healing in this randomized trial, it did not result in a significant advantage in terms of ultimate fusion rates or clinical outcomes for cervical fusion.

Professional Societies

Current specialty society guidelines support the use of noninvasive electrical bone growth stimulators following spinal fusion. They suggest that when choosing a device (capacitive coupling stimulation (CCS) versus pulsed electromagnetic field stimulation (PEMFS), the surgical approach and procedure should be taken into consideration.

American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS)

A 2014 update to the AANS and CNS guidelines for bone growth stimulators as an adjunct for lumbar spinal fusion found no new evidence that conflicted with their original 2005 recommendations supporting the use of CCS to enhance fusion rates in patients at high risk of nonunion undergoing posterior lumbar fusion and PEMFS in high-risk patients following interbody fusion. (Kaiser, 2014).

North American Spine Society (NASS)

The NASS coverage policy recommendations agree with AANS recommendations for spinal indications. According to this document, the current evidence is insufficient to support a coverage recommendation for the use of low intensity pulsed ultrasound or combined magnetic field technology for spinal use, in their opinion, electrical stimulation for augmentation of spinal fusion is indicated for all regions of the spine in individuals at high risk for pseduoarthrosis with specific criteria (i.e., fusion of 3 or more vertebrae, revision spinal fusion, smokers who cannot stop smoking prior to fusion [e.g., trauma], and in the presence of comorbidities). Electrical stimulation is not indicated for a primary spinal fusion without risk factors, spinal fusion of two vertebral levels without risk factors, presence of malignancy, as an adjunct for primary bone healing of a spinal fracture, and as nonsurgical treatment of an established pseduoarthrosis. (NASS, 2016)

A review of four guidelines showed a large disparity of recommendations for use of electrical stimulation in treating vertebral compression fractures (Parriera, 2017).

Ultrasonic Bone-Growth Stimulators

Leighton (2017) reported the results of a systematic review (SR) and meta-analysis of published literature that explored the use of low-intensity pulsed ultrasound as a treatment of nonunions. A total of 13 eligible papers, including one RCT, reporting the results of LIPUS for the treatment of 1441 nonunions of the tibia, humerus, radius, ulna and femur, were evaluated. The quality of the studies was scored using the Methodological Index for Non-Randomized Studies. Quality scores ranged from 5 to 12, with an "ideal" score for a nonrandomized trial being 16. The pooled estimate of effect size for heal rate was 82% (95% CI: 77-87%) for any anatomical site and fracture age of at least 3 months, although statistical heterogeneity was identified across all

primary studies ($Q=41.2$ [$df=12$], $p<0.001$, $Tau^2=0.006$, $I^2=71$). With a stricter definition of nonunion as fracture age of at least eight months duration, the pooled estimate of effect size rose to 84% (95% CI: 77%-91.6%) although heterogeneity remained present: $Q=21$ [$df=8$], $p<0.001$, $Tau^2=0.007$, $I^2=62$). No statistically significant difference was detected between upper and lower extremity long bone nonunions in heal rate. Favorable results of LIPUS intervention were obtained when LIPUS was used as an alternative rather than as an adjuvant to surgery.

Biglari et al. (2016) reported results of a case-controlled study comparing participant with successful and unsuccessful fusion after use of LIPUS for long bone fractures, Data from October 2010 to October 2013 from nonunions in 60 patients treated with EXOGEN® LIPUS therapy were analyzed. Treatment was primarily done on long bones of the lower extremity. All 61 nonunions were examined after treatment, and the rate of healing as well as functional and subjective results were evaluated. Based on clinical and radiological findings, patients were divided into two groups: G1—successful treatment; and G2—unsuccessful treatment. Groups were compared to one another to identify possible factors influencing treatment. Nonunions were classified according to non-union scoring system (NUSS). Bone quality was evaluated according to the classification from Weber and Čech. The gap size, the Paley classification, bone quality, and the bone position were also evaluated. The average gap size was 0.67 ± 0.55 (0–3) cm. In this study, patients with small gap sizes and a low NUSS score benefited most from LIPUS treatment. The strength of this study is the low dropout rate and the regular follow-up scheme. This allowed one to observe the course of the healing process in all patients over an entire year. The authors concluded that “a gap larger than 1 cm was associated with an increased risk of treatment failure.”

In a 2015 Hayes Medical Directory Technology report analyzed the evidence for low intensity pulsed ultrasound as an adjunct to conventional fracture care. The evidence reviewed consisted of RCTs ($n=20$) and studies without controls ($n=6$). Sample size within the studies ranged from 16-101 (for RCTs) and 60 to 1317 for non-controlled studies; follow-up extended from one week to six years after completion of treatment. Hayes concluded the available studies evaluating low-intensity pulsed ultrasound for bone growth stimulation is reasonably safe and that the evidence supports the effectiveness of ultrasound therapy for treatment of nonunion fractures other than the skull or vertebrae in skeletally mature patients. Updated reviews published by Hayes since the initial report indicate there has been no change to the evidence.

Hannemann (2014) published a systematic review with meta-analysis of 13 RCTs comparing pulsed electromagnetic fields (PEMF) or low-intensity pulsed ultrasound (LIPUS) bone growth stimulation with placebo for fresh fractures. Three hundred and fifty-five participants were treated with LIPUS or PEMF, and 382 participants were treated with a placebo device. No significant differences were found in time to radiological union between PEMF or LIPUS and placebo (mean difference = -13.32, 95% CI = -32.71 to 6.06, $p=0.18$), however, in pooled data analyses, heterogenous results that significantly favored PEMF or LIPUS treatment specifically in non-operatively managed fractures were identified (mean difference = -26.65, 95% CI = -50.35 to -2.91, $p = 0.03$). In addition, pooled analysis of the three studies comparing PEMF or LIPUS with placebo of the upper limb found heterogenous results of significantly reduced time to radiological union in this group compared to control (mean difference = -20.23, 95% CI -32.68 to -7.77, $p = 0.001$). There was considerable heterogeneity in the outcome parameter of time to radiological union, which is considered a limitation of the study. The authors concluded that bone growth stimulation with LIPUS or PEMF decreases healing time to radiological union for fresh fractures undergoing non-operative treatment and fractures of the upper limb. The clinical significance of these findings is however unclear and the inconsistency of the findings across outcomes limits the clinical implication of the data for acute fracture.

Another systematic review and network meta-analysis of 27 eligible trials that included patients with a fresh fracture suggested benefit of LIPUS at six months, but the findings were not statistically significant. In patients with an existing nonunion or delayed union, electrical stimulation had a possible benefit over standard care on union rates at three months, but, again, the findings were not statistically significant. The study concluded that there is only very low-quality evidence suggesting a potential benefit of low-intensity versus electrical stimulation in improving union rates at six months in fresh-fracture populations (Ebrahim, 2014). The findings are limited by the inherently indirect nature of network meta-analyses.

Schofer (2010) , published the results of a multicenter, double-blinded, sham-controlled RCT (included in the SR by Leighton) of LIPUS in 101 adult patients who had sustained a tibial shaft fracture that subsequently showed inadequate progress toward healing after at least 16 weeks which was included in the SR by Leighton. The mean improvement in bone mineral density was 1.34 (90% confidence interval (CI) 1.14 to 1.57) times greater for LIPUS-treated subjects compared to sham ($p = 0.002$). A mean reduction in bone gap area also favored LIPUS treatment ($p = 0.014$).

Professional Societies

American Academy of Orthopedic Surgeons (AAOS)

The AAOS published a 2010 clinical practice guideline on the treatment of distal radius fractures in which the recommendation for the use of low-intensity pulsed ultrasound was considered “weak” given the lack of high-quality evidence.

National Institute for Health and Care Excellence (NICE)

The 2018 NICE guidelines state “the evidence for low-intensity pulsed ultrasound to promote healing of delayed-union and non-union fractures raises no major safety concerns. The current evidence on efficacy is inadequate in quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

The FDA regards bone growth stimulators as significant-risk (Class III) devices. Because the list of products used for bone growth stimulation is extensive, see the following website for more information and search by product name in device name section: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>. (Accessed October 1, 2020)

Centers for Medicare and Medicaid Services (CMS)

Medicare covers electrical and electromagnetic bone growth stimulators when criteria are met. Refer to the National Coverage Determination (NCD) for Osteogenic Stimulators 150.2. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist; see the LCDs/LCAs for Osteogenesis Stimulators. (Accessed October 5, 2020)

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Policy History/Revision Information

Date	Summary of Changes
05/01/2021	<p>Template Update</p> <ul style="list-style-type: none"> Replaced reference to “MCG™ Care Guidelines” with “InterQual® criteria” in <i>Instructions for Use</i>
03/01/2021	<p>Template Update</p> <ul style="list-style-type: none"> Reformatted policy; transferred content to new template <p>Coverage Rationale</p> <ul style="list-style-type: none"> Revised language to indicate: <ul style="list-style-type: none"> The use of invasive or noninvasive spinal electrical bone growth stimulator is considered proven and medically necessary as an adjunct to lumbar spinal fusion surgery for individuals with radiographic evidence of skeletal maturity for any of the following indications associated with an increased risk for fusion failure: <ul style="list-style-type: none"> Previously failed fusion at the same site, when minimum of six months has elapsed since the last surgical procedure Spinal fusion performed or to be performed at more than one level as part of a single surgery Comorbid conditions associated with compromised bone healing (e.g., diabetes, obesity, osteoporosis, current tobacco use) Spondylolisthesis grade II or greater The use of invasive or noninvasive spinal electrical bone growth stimulators is unproven and not medically necessary for the treatment of all other indications due to insufficient evidence of efficacy and/or safety The use of ultrasonic bone growth stimulators is proven and medically necessary for the treatment of nonunion of long bone fractures when all of the following criteria are met: <ul style="list-style-type: none"> Fracture gap is less than or equal to 1 cm Radiographic evidence shows ≥ three months persistence of the fracture line without bridging callus Fracture reduced and immobilized Less than 6 months have passed since the date of most recent surgical operation Fracture that is not pathological or associated with malignancy Radiographic evidence of skeletal maturity The use of ultrasonic bone growth stimulators is unproven and not medically necessary for the treatment of all other indications due to insufficient evidence of efficacy and/or safety <p>Definitions</p> <ul style="list-style-type: none"> Added definition of: <ul style="list-style-type: none"> Delayed Union Electrical Bone Growth Stimulation Fracture Union Non-Union Fracture Ultrasonic Bone Growth Stimulation <p>Applicable Codes</p> <ul style="list-style-type: none"> Added CPT code 20974 <p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>Description of Services</i>, <i>Clinical Evidence</i>, <i>CMS</i>, and <i>References</i> sections to reflect the most current information Archived previous policy version CS037TN.M

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

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