

Bone Growth Stimulation

Policy # 00011

Original Effective Date: 05/01/1995

Current Effective Date: 08/01/2026

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

Note: Electrical stimulation of the spine to augment spinal fusion will be reviewed by Carelon based on Carelon Medical Benefits Management clinical appropriateness guidelines for Spine Surgery.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider noninvasive electrical bone growth stimulation (EBGS) as treatment of fracture nonunion or congenital pseudoarthrosis in the appendicular skeleton (the appendicular skeleton includes the bones of the shoulder girdle, upper extremities, pelvis, and lower extremities) to be **eligible for coverage**** when **ALL** of the following criteria are met:

- At least 3 months have passed since the date of fracture; **AND**
- Serial radiographs have confirmed that no progressive signs of healing have occurred; **AND**
- The fracture gap is 1 cm or less; **AND**
- The individual can be adequately immobilized; **AND**
- The individual is of an age likely to comply with non-weight bearing for fractures of the pelvis and lower extremities.

When Services Are Considered Not Medically Necessary

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on available data, the Company considers the use of non-invasive EBGS for other applications in the appendicular skeleton including, but not limited to, the treatment of fresh fractures, delayed union, immediate postsurgical treatment after appendicular skeletal surgery, stress fractures, arthrodesis or failed arthrodesis, or when patient selection criteria are not met to be **not medically necessary.****

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(Note: Delayed union is defined as a decelerating fracture healing process, as identified by serial x-rays.)

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers implantable and semi-invasive electrical bone growth stimulators for use on the appendicular skeleton to be **investigational****.

Based on review of available data, the Company considers the use of low-intensity pulsed ultrasound treatment to be **investigational*** for all indications, including but not limited to the following:

- Treatment of fresh fractures (surgically managed or nonsurgically managed); **OR**
- Treatment of fracture nonunion and delayed union fractures; **OR**
- Treatment of stress fractures, osteotomy, and distraction osteogenesis.

Policy Guidelines

Osteoporosis

Diagnosis of osteoporosis should be supported in medical documentation by one of the following: Patient has central dual x-ray absorptiometry (DXA) bone mineral density (BMD) T-score less than or equal to -2.5 confirming osteoporosis, OR a history of fragility fracture [defined as a major osteoporotic fracture, sustained as a result of a low-level trauma (e.g., a fall from standing height or less) that is associated with low BMD, including vertebral (spine), hip, forearm (wrist/distal radius), and proximal humerus (shoulder) fractures].

Fracture Nonunion

No consensus on the definition of fracture nonunion currently exists. One proposed definition is failure of progression of fracture healing for at least 3 consecutive months (and for at least 6 months following the fracture), accompanied by clinical symptoms of delayed union or nonunion (pain, difficulty bearing weight) (Bhandari et al, 2012).

The original U.S. Food and Drug Administration (FDA) labeling of fracture nonunions defined them as fractures not showing progressive healing after at least 9 months from the original injury. The labeling states: "A nonunion is considered to be established when a minimum of 9 months has elapsed since injury and the fracture site shows no visibly progressive signs of healing for minimum of 3 months." This time frame is not based on physiologic principles, but was included as part of the research design for FDA approval as a means of ensuring homogeneous populations of trial participants, many of whom were serving as their own controls. Others have contended that 9 months represents an arbitrary cutoff point that does not reflect the complicated variables present in fractures

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(ie, degree of soft tissue damage, alignment of the bone fragments, vascularity, quality of the underlying bone stock). Some fractures may show no signs of healing, based on serial radiographs as early as 3 months, while a fracture nonunion may not be diagnosed in others until well after 9 months. The current policy of requiring a 3-month timeframe for lack of progression of healing is consistent with the definition of nonunion as described in the clinical literature.

Delayed Union

Delayed union is defined as a decelerating healing process as determined by serial radiographs, together with a lack of clinical and radiologic evidence of union, bony continuity, or bone reaction at the fracture site for no less than 3 months from the index injury or the most recent intervention. In contrast, nonunion serial radiographs (described above) show no evidence of healing. When lumped together, delayed union and nonunion are sometimes referred to as “united fractures.”

Fresh Fracture

A fracture is most commonly defined as “fresh” for 7 days after its occurrence. Most fresh closed fractures heal without complications with the use of standard fracture care (ie, closed reduction, cast immobilization).

Background/Overview

Electrical Bone Growth Stimulation of the Appendicular Skeleton

Treatment of Delayed and Nonunion Fractures

Individuals with recognized delayed fracture unions might begin by reducing the risk factors for delayed unions or nonunions but may progress to surgical repair if it persists.

Electrical and Electromagnetic Bone Growth Stimulators

Different applications of electrical and electromagnetic fields have been used to promote healing of delayed and nonunion fractures: invasive, noninvasive, and semi-invasive.

Invasive Stimulators

Invasive devices require surgical implantation of a current generator in an intramuscular or subcutaneous space, with an accompanying electrode implanted within the fragments of bone graft at the fusion site. The implantable device typically remains functional for 6 to 9 months after implantation. Although the current generator is removed in a second surgical procedure when stimulation is completed, the electrode may or may not be removed. Implantable electrodes provide constant stimulation at the nonunion or fracture site but carry increased risks associated with implantable leads.

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Noninvasive Stimulators

Noninvasive electrical bone growth stimulators generate a weak electrical current within the target site using pulsed electromagnetic fields, capacitive coupling, or combined magnetic fields. In capacitive coupling, small skin pads/electrodes are placed on either side of the fusion site and worn for 24 hours a day until healing occurs or up to 9 months. In contrast, pulsed electromagnetic fields are delivered via treatment coils placed over the skin and worn for 6 to 8 hours a day for 3 to 6 months. Combined magnetic fields deliver a time-varying magnetic field by superimposing the time-varying magnetic field onto an additional static magnetic field. This device involves a 30-minute treatment per day for 9 months. Patient compliance may be an issue with externally worn devices.

Semi-Invasive Stimulators

Semi-invasive (semi-implantable) stimulators use percutaneous electrodes and an external power supply, obviating the need for a surgical procedure to remove the generator when treatment is finished.

Low Intensity Pulsed Ultrasound Fracture Healing Device

Bone Fractures

An estimated 178 million new fractures were reported worldwide in 2019. Most bone fractures heal spontaneously over several months following standard fracture care (closed reduction, if necessary, followed by immobilization with casting or splinting). However, approximately 5% to 10% of all fractures have delayed healing, resulting in continued morbidity and increased utilization of health care services. Factors contributing to a nonunion include which bone is fractured, fracture site, the degree of bone loss, time since injury, the extent of soft tissue injury, and patient factors (eg, smoking, diabetes, systemic disease).

Fracture Nonunion

There is no standard definition of a fracture nonunion. The U.S. Food and Drug Administration (FDA) has defined nonunion as when "a minimum of 9 months has elapsed since injury, and the fracture site shows no visibly progressive signs of healing for a minimum of 3 months." Other definitions cite 3 to 6 months of time from the original injury, or simply when serial radiographs fail to show any further healing. These definitions do not reflect the underlying conditions in fractures that affect healing, such as the degree of soft tissue damage, alignment of the bone fragments, vascularity, and quality of the underlying bone stock.

Delayed Union

Delayed union is generally considered a failure to heal between 3 and 9 months post-fracture, after which the fracture site would be considered a nonunion. The delayed union may also be defined as a decelerating bone healing process, as identified in serial radiographs. (In contrast, nonunion serial radiographs show no evidence of healing.) It is important to include both radiographic and clinical criteria to determine fracture healing status. Clinical criteria include the lack of ability to bear weight, fracture pain, and tenderness on palpation.

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Treatment

Low-intensity pulsed ultrasound (LIPUS) has been proposed to accelerate healing of fractures. Low-intensity pulsed ultrasound is believed to alter the molecular and cellular mechanisms involved in each stage of the healing process (inflammation, soft callus formation, hard callus formation, and bone remodeling). The mechanism of action at the cellular level is not precisely known, but it is theorized that LIPUS may stimulate the production or the activities of the following compounds that contribute to the bone healing process: cyclooxygenase-2, collagenase, integrin proteins, calcium, chondroblasts, mesenchymal cells, fibroblasts, and osteoblasts.

LIPUS treatment is self-administered, once daily for 20 minutes, until the fracture has healed.

FDA or Other Governmental Regulatory Approval

Electrical Bone Growth Stimulation of the Appendicular Skeleton

Table 1 summarizes the FDA cleared or approved noninvasive electrical bone growth stimulator devices. No implantable or semi-invasive electrical bone growth stimulator devices with the FDA approval or clearance were identified.

The FDA has approved labeling changes for electrical bone growth stimulators that remove any time frame for the diagnosis. In September 2020, FDA considered the reclassification of noninvasive electrical bone growth stimulators from Class 3 to the lower-risk Class 2 category. As of March 2025, however, the devices remain Class 3.

FDA product code LOF.

Table 1. U.S. Food and Drug Administration-Approved Noninvasive Electrical Bone Growth Stimulator devices

Device	Indication	Manufacturer	Date Approved	PMA No./Device Code
BIO Osteogen System 204 (now EBI Bone Healing System)	Indicated for the treatment of a variety of conditions, including non-unions, congenital pseudarthrosis, and certain fractures.	EBI (now Highridge Medical)	1979	P790002
OrthoPak Non-invasive Bone Growth Stimulator System	Indicated for the treatment of an <i>established nonunion</i> acquired secondary to trauma, excluding vertebrae and all flat bones.	EBI (now Highridge Medical)	1986	P850022/S018

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Physio-Stim®†	Indicated for the treatment of an <i>established nonunion</i> acquired secondary to trauma, excluding vertebrae and all flat bones.	Orthofix	1986	P850007
OrthoLogic (TM) 1000 Bone Growth Stimulator	Indicated for the noninvasive treatment of an <i>established nonunion</i> acquired secondary to trauma, excluding vertebrae and all flat bones.	DJO (now Enovis)	1994	P910066
Osteogen(R) D40 Implantable Bone Growth Stimulator	Indicated for treatment of nonunions of long bones.	EBI (now Highridge Medical)	2000	P790005

Low Intensity Pulsed Ultrasound Fracture Healing Device

In 1994, the Sonic Accelerated Fracture Healing System (SAFHS®†; renamed Exogen 2000®† and Exogen 4000+, now Exogen®† Ultrasound Bone Healing System; Bioventus) was approved by the FDA through the premarket approval process for treatment of fresh, closed, posteriorly displaced distal radius (Colles) fractures and fresh, closed, or grade 1 open tibial diaphysis fractures in skeletally mature individuals when these fractures are orthopedically managed by closed reduction and cast immobilization. In February 2000, the labeled indication was expanded to include the treatment of established nonunions, excluding skull and vertebra. The AccelStim™† Bone Growth Stimulator (Orthofix US) was FDA approved in 2022 for accelerating time to healed fracture for fresh, closed, posteriorly displaced distal radius fractures and fresh, closed, or Grade I open tibial diaphysis fractures and for established non-unions in skeletally mature adults. The Manafuse®† Bone Growth Stimulator (ManaMed, now Enovis) was FDA approved in 2025 for the same indications as Exogen. FDA product code: LOF.

Table 2 summarizes the FDA cleared or approved LIPUS devices.

Table 2 U.S. Food and Drug Administration-Approved Low-Intensity Pulsed Ultrasound Devices

Device	Indication	Manufacturer	Date Approved	PMA No./Device Code
Exogen®† Ultrasound Bone Healing System	Treatment of fresh, closed, posteriorly displaced distal radius (Colles)	Bioventus	1994;2000	P900009;P900009/S006

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	fractures and fresh, closed, or grade 1 open tibial diaphysis fractures in skeletally mature individuals when these fractures are orthopedically managed by closed reduction and cast immobilization. Expanded to non-invasive treatment of established nonunions^a, excluding skull and vertebra.			
AccelStim™ [‡] Bone Growth Stimulator	Accelerating time to healed fracture for fresh, closed, posteriorly displaced distal radius fractures and fresh, closed, or Grade I open tibial diaphysis fractures and for established non-unions in skeletally mature adults	Orthofix	2022	P210035

^a The device was formerly named Sonic Accelerated Fracture Healing System Model 2A (SAHFS^{®‡})

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^b A nonunion is considered to be established when the fracture site shows no visibly progressive signs of healing.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

Electrical Bone Growth Stimulation of the Appendicular Skeleton

Description

In the appendicular skeleton, electrical stimulation with either implantable electrodes or noninvasive surface stimulators has been investigated to facilitate the healing of fresh fractures, stress fractures, delayed union, nonunion, congenital pseudarthrosis, and arthrodesis.

Summary of Evidence

Noninvasive Electrical Bone Growth Stimulation

For individuals who have fracture nonunion who receive noninvasive electrical bone growth stimulation, the evidence includes randomized controlled trials (RCTs) and systematic reviews of RCTs. Relevant outcomes are symptoms, change in disease status, and functional outcomes. The U.S. Food and Drug Administration (FDA) has approved noninvasive electrical bone growth stimulation for fracture nonunions and congenital pseudarthrosis in the appendicular skeleton, based largely on studies with patients serving as their controls. There is also evidence from 2 small sham-controlled randomized trials that noninvasive electrical stimulators improve fracture healing for patients with fracture nonunion. There are few nonsurgical options in this population, and the pre-post studies of patients with nonhealing fractures support the efficacy of the treatment. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have delayed fracture union who receive noninvasive electrical bone growth stimulation, the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are symptoms, change in disease status, and functional outcomes. Available RCTs on the delayed union of fractures were limited by small sample sizes and did not show significant differences in outcomes between study groups. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have fresh fracture(s) who receive noninvasive electrical bone growth stimulation, the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are symptoms, change in disease status, and functional outcomes. A meta-analysis of 5 RCTs found no

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statistically significant benefit of electrical bone growth stimulation for fresh fractures. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have stress fracture(s) who receive noninvasive electrical bone growth stimulation, the evidence includes an RCT. Relevant outcomes are symptoms, change in disease status, and functional outcomes. This well-conducted RCT found that, although an increase in the hours of use per day was associated with a reduction in the time to healing, there was no difference in the rate of healing between treatment and placebo. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have had surgery of the appendicular skeleton who receive noninvasive electrical bone growth stimulation, the evidence includes 2 small RCTs. Relevant outcomes are symptoms, change in disease status, and functional outcomes. Although the results of 1 trial suggest benefits to the bone stimulation in decreased time to union, clinical outcomes were not assessed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Implantable and Semi-Invasive Bone Growth Stimulation

For individuals who have fracture, pseudarthrosis, or who have had surgery of the appendicular skeleton who receive implantable and semi-invasive electrical bone growth stimulation, the evidence includes a small number of case series. Relevant outcomes are symptoms, change in disease status, and functional outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Low Intensity Pulsed Ultrasound Fracture Healing Device

Description

Low-intensity pulsed ultrasound has been investigated as a technique to accelerate healing of fresh fractures, surgically treated closed fractures, delayed unions, nonunions, stress fractures, osteotomy sites, and distraction osteogenesis. Low-intensity pulsed ultrasound is administered using a transducer applied to the skin surface overlying the fracture site.

Summary of Evidence

For individuals who have fresh fractures (surgically or nonsurgically managed) who receive low-intensity pulsed ultrasound (LIPUS) as an adjunct to routine care, the evidence includes randomized controlled trials (RCTs) and several meta-analyses. Relevant outcomes are symptoms, morbid events, functional outcomes, and quality of life. The evidence base has evolved with the publication of a large RCT and meta-analysis significantly shifting the weight of the evidence. Conclusions based on several earlier and small RCTs, rated at high-risk of bias, showed a potential benefit; however, the large RCT published in 2016, rated at low-risk of bias, showed no benefit. A 2017 meta-analysis including only trials with low-risk of bias found no difference in days to full weight-bearing, pain reduction, or days to radiographic healing. Similarly, the overall results of the meta-

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analysis found no significant difference in return to work, subsequent operations, or adverse events. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have fracture nonunion or delayed union fracture who receive LIPUS as an adjunct to routine care including surgery, if appropriate, the evidence includes systematic reviews, RCTs, and uncontrolled studies. Relevant outcomes are symptoms, morbid events, functional outcomes, and quality of life. There are 2 meta-analyses (2017) without controlled comparative results. A third meta-analysis, which included all types of fractures, identified 3 RCTs of patients with nonunion; however, all 3 trials were considered at high-risk of bias (one published as a thesis). One meta-analysis specific to individuals with instrumented, infection, or fragility-related non-union found few RCTs and results were largely based on case series. A Canadian multicenter, prospective, double-blinded RCT (SNAPU) trial evaluated whether active LIPUS accelerates the time to union following surgery for scaphoid nonunion, involving 142 subjects (69 in the active LIPUS group and 73 in the sham group). The study found no significant differences in the time to union ($p = .854$) or any secondary outcomes, except for wrist flexion at baseline ($p = .008$) and final follow-up ($p = .043$). Subgroup analyses based on device compliance showed no differences in union rates or time to union between compliance subgroups. Of the earlier 2 RCTs, one did not include functional outcomes; the second trial had a small sample size and did not describe the randomization procedure. The observational study reported similar healing rates with LIPUS and surgery, although the retrospective nature of the study limits meaningful interpretation of these results. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have stress fractures, osteotomy sites, or distraction osteogenesis who receive LIPUS as an adjunct to routine care, the evidence includes only lower quality studies consisting of small RCTs, retrospective comparative observational studies, and one meta-analysis for distraction osteogenesis. Relevant outcomes are symptoms, morbid events, functional outcomes, and quality of life. Results do not generally include functional outcomes and results across various outcomes, primarily time to radiographic healing, are inconsistent. The meta-analysis of 3 trials using LIPUS ultrasound for distraction osteogenesis reported no statistically significant differences in physiological or functional outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

PRACTICE GUIDELINES AND POSITION STATEMENTS

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

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Electrical Bone Growth Stimulation of the Appendicular Skeleton

The American Academy of Orthopaedic Surgeons (AAOS) has provided the following guidance on nonsurgical treatment options for specific conditions:

Nonunions (May 2024)

- “In addition to immobilizing the nonunion, your doctor may have you use a bone stimulator. This small device delivers ultrasonic or pulsed electromagnetic waves that stimulate healing. The patient places the stimulator on the skin over the nonunion for 20 minutes to several hours daily. This treatment must be used every day to be effective.”

Stress Fractures of the Fifth Metatarsal Base (March 2022)

- “Nonsurgical management typically consists of non-weightbearing immobilization (cast or boot) for at least 6 weeks. Your physician may prescribe vitamin D, a bone stimulator, or other methods to increase the healing potential. You are usually not able to return to sports until 12 weeks post-injury.”

Low Intensity Pulsed Ultrasound Fracture Healing Device

National Institute for Health and Care Excellence

In 2019, the National Institute for Health and Care Excellence (NICE) published evidence-based recommendations on EXOGEN ultrasound bone healing system for long bone fractures with non-union or delayed healing:

“The case for adopting the EXOGEN ultrasound bone healing system to treat long bone fractures with **non-union** (failure to heal after 9 months) is supported by the clinical evidence, which shows high rates of fracture healing.”

In 2018, the National Institute for Health and Care Excellence (NICE) published guidance on the use of low-intensity pulsed ultrasound (LIPUS) to promote healing of fresh fractures at low-risk of non-healing. The guidance states that "Current evidence does not show efficacy. Therefore, this procedure should not be used for this indication."

In 2018, the NICE published guidance on the use of low-intensity pulsed ultrasound to promote healing of fresh fractures at high-risk of non-healing. The guidance states that "Current evidence on efficacy is very limited in quantity and quality. Therefore, this procedure should only be used in the context of research."

In 2018, the NICE published guidance on the use of low-intensity pulsed ultrasound to promote healing of delayed and nonunion fractures. The guidance states that "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."

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In 2013, the NICE published guidance on Exogen for the treatment of long-bone fractures with nonunion and delayed fracture healing. The NICE concluded that use of the Exogen bone healing system to treat long-bone fractures with nonunion is supported by "clinical evidence" and "cost savings ... through avoiding surgery." For long-bone fractures with delayed healing, defined as no radiologic evidence of healing after 3 months, there was "some radiologic evidence of improved healing." However, due to "substantial uncertainties about the rate at which bone healing progresses without adjunctive treatment between 3 and 9 months after fracture" and need for surgery, "cost consequences" were uncertain. In 2019, the Exogen guidance was updated with a review of studies published after June 2012. The review decision stated, "Overall the additional clinical evidence identified since the guidance was published in 2013 supports the current recommendations." The reviewers did not consider the Schandelmaier et al (2017) systematic review because it pooled fresh fractures and distraction osteogenesis alongside non-unions.

American Academy of Orthopaedic Surgeons

In 2020, the American Academy of Orthopaedic Surgeons published updated guidelines on the treatment of distal radius fractures. Although the Academy issued a limited recommendation for the use of low-intensity pulsed ultrasound for adjuvant treatment of distal radius fractures in its prior 2009 guidelines, low-intensity pulsed ultrasound was not mentioned in the updated guidelines.

Centers for Medicare and Medicaid Services (CMS)

Electrical Bone Growth Stimulation of the Appendicular Skeleton

Noninvasive stimulators are covered by Medicare for the following indications:

- “Nonunion of long bone fractures;
- Failed fusion, where a minimum of 9 months has elapsed since the last surgery;
- Congenital pseudarthroses....”

Invasive stimulators are covered for:

- “Nonunion of long bone fractures.”

“Effective April 1, 2000, nonunion of long bone fractures is considered to exist only when serial radiographs have confirmed that fracture healing has ceased for 3 or more months prior to starting treatment with the electrical osteogenic stimulator. Serial radiographs must include a minimum of 2 sets of radiographs, each including multiple views of the fracture site, separated by a minimum of 90 days.”

Low Intensity Pulsed Ultrasound Fracture Healing Device

Effective 2001, ultrasonic osteogenic stimulators were covered as medically reasonable and necessary for the treatment of nonunion fractures. Nonunion fractures of the skull, vertebrae, and those that are tumor-related are excluded from coverage. Ultrasonic osteogenic stimulators may not

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be used concurrently with other noninvasive osteogenic devices. Ultrasonic osteogenic stimulators for fresh fractures and delayed unions are not covered.

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10/18/2001	Medical Policy Committee review. Policy revised to include ultrasound accelerated healing devices and noninvasive and invasive bone growth stimulators.
11/12/2001	Managed Care Advisory Council approval
06/24/2002	Format revision. No substance change to policy.
11/18/2003	Medical Policy Committee review. Format revision. Policy name changed from Fracture Healing Devices to Bone Growth Stimulation.
01/26/2004	Managed Care Advisory Council approval
03/01/2005	Medical Director review
03/15/2005	Medical Policy Committee review
04/04/2005	Managed Care Advisory Council approval
04/05/2006	Medical Director review
04/19/2006	Medical Policy Committee review. Format revision, including addition of FDA and or other governmental regulatory approval
04/04/2007	Medical Director review
04/18/2007	Medical Policy Committee approval. Coverage eligibility unchanged. Rationale/Source updated
04/02/2008	Medical Director review
04/16/2008	Medical Policy Committee approval. Coverage eligibility unchanged. Removed criterion from patient selection criteria "the fracture gap is 1cm or less." Rationale/Source updated.
04/02/2009	Medical Director review
04/15/2009	Medical Policy Committee approval. Coverage eligibility unchanged.
04/08/2010	Medical Policy Committee approval
04/21/2010	Medical Policy Implementation Committee approval. Added noninvasive electrical bone stimulation as a treatment of patients with failed lumbar spinal fusion to be eligible for coverage. Added implantable and semi-invasive electrical bone growth stimulators to be investigational. Added semi-invasive electrical stimulation as an adjunct to lumbar fusion surgery and for failed lumbar fusion to be investigational. Added invasive, semi-invasive and noninvasive electrical stimulation as an adjunct to cervical fusion surgery and for failed cervical spine fusion to be investigational. Updated rationale and references.
04/07/2011	Medical Policy Committee review
04/13/2011	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/06/2011	Medical Policy Committee review
10/19/2011	Medical Policy Implementation Committee approval. "Based on review of available data, the Company may consider low-intensity ultrasound treatment may

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be considered as a treatment of delayed union of bones excluding the skull and vertebra to be eligible for coverage” was added to the coverage statement. Used to be investigational. “Based on available data, the Company considers implantable and semi-invasive electrical bone growth stimulators to be investigational” was removed from policy.

06/28/2012 Medical Policy Committee review

07/27/2012 Medical Policy Implementation Committee approval. Criteria for low –intensity ultrasound for fresh fractures revised.

02/20/2013 Medical Policy Implementation Committee approval. Changed criteria statement for electrical bone growth stimulation of the spine from “potential” spinal fusion surgery to “lumbar” spinal fusion surgery for clarification. Deleted the second criteria bullet for the use of electrical bone growth stimulation of the spine as a treatment for patients with failed spinal fusion, since this is a duplicate coverage statement in the policy.

06/06/2013 Medical Policy Committee review

06/25/2013 Medical Policy Implementation Committee approval. Replaced “lumbar” with “spinal” in the first bullet of the criteria for electrical bone growth stimulation of the spine, so that all spinal fusions are covered with criteria. Deleted “lumbar” from the non-invasive electrical bone growth stimulation coverage statement for failed spinal fusions. Deleted the investigational statement regarding cervical fusions.

09/05/2013 Medical Policy Committee review

09/18/2013 Medical Policy Implementation Committee approval. “Based on review of available data, the Company considers implantable and semi-invasive electrical bone growth stimulators for use on the appendicular skeleton to be investigational” was added to the coverage statement.

09/04/2014 Medical Policy Committee review

09/17/2014 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.

09/03/2015 Medical Policy Committee review

09/23/2015 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

03/03/2016 Medical Policy Committee review

03/16/2016 Medical Policy Implementation Committee approval. Reorganized and clarified coverage section.

10/01/2016 Coding update

01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes

03/02/2017 Medical Policy Committee review

03/15/2017 Medical Policy Implementation Committee approval. Immediate postsurgical treatment after appendicular skeletal surgery, stress fractures, and fresh surgically

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	treated closed fractures added to existing INV statements. Clarified language in coverage statements. Reduced size of rationale section and added guidelines section.
08/03/2017	Medical Policy Committee review
08/23/2017	Medical Policy Implementation Committee approval. Added criteria bullet for electrical bone growth stimulation of the appendicular skeleton, "The fracture gap is 1 cm or less" and changed the verbiage of the last criteria bullet to, "The patient is of an age likely to comply with non-weight bearing for fractures of the pelvis and lower extremities. Policy coverage changed to include AIM guidelines for primary cervical or lumbar fusion. Changed coverage for the use of low intensity ultrasound from eligible for coverage with criteria to investigational.
08/09/2018	Medical Policy Committee review
08/15/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/07/2019	Medical Policy Committee review
03/20/2019	Medical Policy Implementation Committee approval. Added "at any spinal level" regarding fusion revision in the Patient Selection Criteria for Primary Cervical or Lumbar Fusion. Added risk factor criteria for cervical non-invasive bone growth stimulation. Deleted non-invasive bone growth stimulation criteria bullet regarding current smokers.
11/07/2019	Medical Policy Committee review
11/13/2019	Medical Policy Implementation Committee approval. Coverage and criteria for thoracic or lumbar fusion and coverage criteria for cervical fusion revised to track AIM Guidelines.
09/10/2020	Coding update
11/05/2020	Medical Policy Committee review
11/11/2020	Medical Policy Implementation Committee approval. Added "pulsed" to low-intensity ultrasound to read low-intensity pulsed ultrasound in the investigational statement. Coverage eligibility unchanged.
11/04/2021	Medical Policy Committee review
11/10/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/03/2022	Medical Policy Committee review
11/09/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/02/2023	Medical Policy Committee review
11/08/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/07/2024	Medical Policy Committee review
11/13/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

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11/06/2025 Medical Policy Committee review
11/12/2025 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/07/2026 Medical Policy Committee review
05/13/2026 Medical Policy Implementation Committee review
06/18/2026 Medical Quality Management Committee approval. Medical policy is repurposed to address only electrical bone growth stimulation of the appendicular skeleton and low-intensity pulsed ultrasound (LIPUS). Electrical bone growth stimulation of the spine as an adjunct to spinal fusion will be addressed in Carelon Spine Surgery program for effective date 08/01/2026. Changed the following investigational statements to not medically necessary: Non-invasive EBGs for other applications in the appendicular skeleton including, but not limited to, the treatment of fresh fractures, delayed union, immediate postsurgical treatment after appendicular skeletal surgery, stress fractures, arthrodesis or failed arthrodesis, or when patient selection criteria are not met.

Next Scheduled Review Date: 11/2026

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)†, copyright 2025 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Louisiana Blue Medical Policy Coverage Guidelines is with Louisiana Blue and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Louisiana Blue Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Louisiana Blue Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

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Code Type	Code
CPT	20974, 20975, 20979
HCPCS	E0747, E0748, E0749, E0760 Delete code effective 08/01/2026: E0748
ICD-10 Diagnosis	All related Diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan's authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan.