LOUISIANA BLUE

Bone Growth Stimulation

Policy # 00011
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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.

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.****

Patient Selection Criteria for the use of Electrical Bone Growth Stimulation (EBGS) of the Appendicular Skeleton
Coverage eligibility for the use of noninvasive EBGS of the appendicular skeleton as a treatment of fracture nonunion will be considered 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.

Based on review of available data, the Company may consider noninvasive electrical bone growth stimulation (EBGS) of the spine to augment primary thoracic or lumbar spinal fusion in individuals at high risk for pseudoarthrosis to be **eligible for coverage.****

Patient Selection Criteria for Thoracic or Lumbar Fusion
Coverage eligibility for the use of noninvasive electrical bone growth stimulation (EBGS) of the spine to augment primary thoracic or lumbar spinal fusion in individuals at high risk for pseudoarthrosis will be considered when **ANY** of the following criteria are present:

- Fusion revision (e.g., repeat surgery due to prior unhealed fusion attempt) when at least 6 months have passed since the original surgery and imaging studies confirm that healing has not progressed in the preceding 3 months; **OR**
- Fusion performed at two (2) or more adjacent levels*; **OR**
- Presence of **ANY** of the following risk factors:
    - Diabetes; **OR**
    - Metabolic bone disease (including osteoporosis or osteopenia, and bone disease secondary to renal disease, nutritional deficiency, or conditions in which bone healing is likely to be compromised; **OR**
    - Immunocompromised; **OR**
    - Systemic vascular disease; **OR**
    - History of long term use of corticosteroids; **OR**
    - Active nicotine use.

**Defined as two or more motion segments (3 vertebrae); alternatively, one level includes the upper and lower vertebral segment and the intervening disc space, e.g., L4-L5 is one level.*

Based on review of available data, the Company may consider noninvasive electrical bone growth stimulation (EBGS) of the spine to augment spinal fusion in all regions of the cervical spine in individuals at high risk for pseudoarthrosis to be **eligible for coverage.****

Patient Selection Criteria for Cervical Fusion

Coverage eligibility for the use of noninvasive electrical bone growth stimulation (EBGS) of the spine to augment spinal fusion in all regions of the cervical spine in individuals at high risk for pseudoarthrosis when **ANY** of the following criteria are present:

- Fusion revision (e.g., repeat surgery due to prior unhealed fusion attempt) when at least 6 months has passed since the original surgery and imaging studies confirm that healing has not progressed in the preceding 3 months; **OR**
- Fusion performed at three (3) or more adjacent levels** for cervical fusion when **ANY** of the following risk factors are present:
    - Diabetes; **OR**
    - Osteoporosis (see Policy Guidelines); **OR**
    - Active nicotine use.

***Defined as three or more motion segments (4 vertebrae).*

When Services Are Considered Investigational

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 invasive or non-invasive EBGS for other applications in the appendicular skeleton including, but not limited to, the treatment 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 **investigational***

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

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 electric bone growth stimulation (EBGS) for primary cervical or lumbar fusion and for all spinal levels when patient selection criteria are not met to be **investigational***, including but not limited to the following:

- Treatment of spondylolysis or pars interarticularis defect; **OR**
- Semi-invasive EBGS for any indication; **OR**
- As an adjunct for primary bone healing of a spinal fracture; **OR**
- As a nonsurgical treatment of an established pseudoarthrosis.

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].

Electrical Bone Growth Stimulation

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 (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 "ununited 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 stimulation involves the surgical implantation of a cathode at the fracture site to produce direct current electrical stimulation. Invasive devices require surgical implantation of a current generator in an intramuscular or subcutaneous space, while an electrode is implanted within the fragments of bone graft at the fusion site. The implantable device typically remains functional for 6 to 9 months after implantation, and 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.

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 (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.

Noninvasive Electrical Bone Growth Stimulation of the Spine
Bone growth stimulators, also known as osteogenesis stimulators, are utilized to promote bone healing in spinal fusion through delivery of electrical current to the fusion site. Noninvasive devices are worn externally, beginning at any time from the date of surgery until up to 6 months after surgery.

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.

Treatment
Low-intensity pulsed ultrasound 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 low-intensity pulsed ultrasound 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.

Low-intensity pulsed ultrasound treatment is self-administered, once daily for 20 minutes, until the fracture has healed.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Electrical Bone Growth Stimulation of the Appendicular Skeleton
In 1984, the noninvasive OrthoPak®‡ Bone Growth Stimulator (BioElectron, now Zimmer Biomet) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process for treatment of fracture nonunion. Pulsed electromagnetic field systems with the 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; and 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.

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 2024, however, the devices remain Class 3.

No semi-invasive electrical bone growth stimulator devices with FDA approval or clearance were identified.

FDA product code LOF.

Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures
The following implantable device was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process:

- In 1986, the OsteoStim®‡ (Electro-Biology), which may also be marketed under the trade name SPF (Biomet) was approved.

The following noninvasive bone growth stimulators have been approved by the FDA through the premarket approval process:

- In 1999, the SpinalPak®‡ bone growth stimulator system (Biolectron, a subsidiary of Electro-Biology), a capacitive coupling system, was approved for use as an adjunct to primary lumbar spinal fusion at 1 or 2 levels.
- In 1979, the EBI Bone Healing System®‡ (Biolectron, a subsidiary of Electro-Biology), a pulsed electromagnetic field system, was approved for nonunions, failed fusions, and congenital pseudoarthroses. The device is secured with a belt around the waist.
- In 1994, the SpinaLogic Bone Growth Stimulator®‡ (Regentek, a division of dj Orthopedics [formerly OrthoLogic]) was approved as a combined magnetic field portable device. This device is secured with a belt around the waist.
- In 1996, the Spinal-Stim Lite®‡ (Orthofix) was approved as a spinal adjunct to the Physio-Stim®‡. The Spinal-Stim Lite®‡ device was approved to increase the probability of fusion success and as a nonoperative treatment for the salvage of failed spinal fusion, where a minimum of 9 months has elapsed since the last surgery.
- In 2004, the Stim®‡ (Orthofix), a pulsed electromagnetic field system, was approved as an adjunct to cervical fusion surgery in patients at high-risk for nonfusion.
- In 2020, the ActaStim-S Spine Fusion Stimulator (Theragen, Inc.), was approved as an adjunct electrical treatment to primary lumbar spinal fusion surgery for one or two levels. This device is secured with a belt around the waist.

No semi-invasive electrical bone growth stimulator devices were identified with the FDA approval or clearance.

FDA product codes: LOE (invasive bone growth stimulator), LOF (noninvasive bone growth stimulator).

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.

FDA product code: LPQ.

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 federal regulations, other plan medical policies, and accredited national guidelines.

Electrical Bone Growth Stimulation of the Appendicular Skeleton

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 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

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 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-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 low-intensity pulsed ultrasound as an adjunct to routine care including surgery, if appropriate, the evidence includes only lower quality studies consisting of a small systematic review in scaphoid nonunions, a meta-analysis of nonunion in various locations, a meta-analysis in individuals with specific risk factors, 2 low-quality RCTs, and 1 observational comparative study. Relevant outcomes are symptoms, morbid events, functional outcomes, and quality of life. Of the 2 RCTs, one did not

include functional outcomes. The second RCT had a small sample size and did not describe the randomization procedure. The observational study reported similar healing rates with low-intensity pulsed ultrasound 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 low-intensity pulsed ultrasound 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 low-intensity pulsed 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.

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 to promote healing of fresh fractures at low-risk of non-healing. The guidance states that the "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 the "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 the "current evidence on efficacy is inadequate in quality. Therefore, this procedure should only be used with special arrangements for clinical governances, consent and audit or research."

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."

Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures

Medicare covers noninvasive electrical stimulators for the following:

- "Failed fusion, where a minimum of 9 months has elapsed since the last surgery" and
- "…as an adjunct to spinal fusion surgery for patients at high risk of pseudoarthrosis due to previously failed spinal fusion at the same site or for those undergoing multiple level fusion. A multiple level fusion involves 3 or more vertebrae (e.g., L3-L5, L4-S1, etc)."

Medicare covers invasive electrical stimulators:

- "…as an adjunct to spinal fusion surgery for patients at high risk of pseudoarthrosis due to previously failed spinal fusion at the same site or for those undergoing multiple level fusion. A multiple level fusion involves 3 or more vertebrae (e.g., L3-L5, L4-S1, etc)."

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

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Policy # 00011
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Current Effective Date: 02/23/2025

Policy History

Original Effective Date: 05/01/1995
Current Effective Date: 02/23/2025

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 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 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.

Next Scheduled Review Date: 11/2025

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2023 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.

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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:

Code Type	Code
CPT	20974, 20975, 20979
HCPCS	E0747, E0748, E0749, E0760
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.

‡ 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.