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MEDICAL POLICY – 1.01.537

Low Intensity Pulsed Ultrasound Fracture Healing Device

BCBSA Ref. Policy:	1.01.05	
Effective Date:	Jul. 1, 2025	RELATED MEDICAL POLICIES:
Last Revised:	Jun. 23, 2025	7.01.07 Electrical Bone Growth Stimulation of the Appendicular Skeleton
Replaces:	1.01.531	7.01.85 Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

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Introduction

Ultrasound is a sound wave that humans can't hear. Ultrasound has been tried to help broken bones heal. It was believed that ultrasound stimulates growth of new bone by activating the growth of new bone cells. The latest large studies, however, show there isn't enough evidence to conclude that ultrasound waves help bones heal. Using ultrasound on bones that were cut during surgery or broken is not medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Treatment	Medical Necessity
Low-intensity pulsed ultrasound	**Low-intensity pulsed ultrasound is considered not medically necessary for the treatment of the following:** • Fresh fractures (surgically managed or nonsurgically managed) • Fracture nonunion and delayed union fractures • Stress fractures, osteotomy, and distraction osteogenesis **Note:** See **Definition of Terms** for more information.

Coding

Code	Description
CPT	
20979	Low intensity ultrasound stimulation to aid bone healing, noninvasive (nonoperative)
HCPCS	
E0760	Osteogenesis stimulator, low intensity ultrasound, non-invasive

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

Definition of Terms

Fresh (acute) fracture: There is no standard definition of a "fresh" fracture. A fracture is most commonly defined as fresh for 7 days after the fracture occurs, but there is definitional variability. For example, one study defined fresh as less than 5 days after fracture, while another defined fresh as up to 10 days post-fracture. Most fresh closed fractures heal without complications using standard fracture care (i.e., closed reduction and cast immobilization).

Nonunion: There is no consensus on the definition of nonunion. One definition is a failure of progression of fracture healing for at least 3 consecutive months (and at least 6 months post-fracture) accompanied by clinical symptoms of delayed/nonunion (pain, difficulty weight bearing).

The definition of nonunion in the US Food and Drug Administration (FDA) labeling suggests that nonunion is considered established when the fracture site shows no visibly progressive signs of healing, without providing guidance on the timeframe of observation. The following selection criteria are consistent with those proposed for electrical stimulation as a treatment of nonunions (see **Related Policies**):

- At least 3 months have passed since the date of the 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, based on age, is likely to comply with non-weight bearing

Note: Electrical bone growth stimulation for healing is addressed in a separate medical policy (see **Related Policies**).

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.

Benefit Application

The transducer used for ultrasound treatment is categorized as durable medical equipment.

Evidence Review

Description

Low-intensity pulsed ultrasound (LIPUS) 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. LIPUS is administered using a transducer applied to the skin surface overlying the fracture site.

Background

Bone Fractures

An estimated 178 million new fractures were reported worldwide in 2019.[1]. 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.[2] 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 individual factors (e.g., smoking, diabetes, systemic disease).[2]

Fracture Nonunion

There is no standard definition of a fracture nonunion.[3] The US 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 three to six 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 three and nine 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

LIPUS has been proposed to accelerate healing of fractures. LIPUS 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.

Summary of Evidence

For individuals who have fresh fractures (surgically or nonsurgically managed) who receive LIPUS as an adjunct to routine care, the evidence includes randomized controlled trials (RCTs) and several meta-analyses. The relevant outcomes are symptoms, morbid events, functional outcomes, and quality of life (QOL). 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 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. The relevant outcomes are symptoms, morbid events, functional outcomes, and QOL. Results do not generally include functional outcomes and results across various outcomes, primarily time to radiographic healing, are inconsistent. The meta-analysis of three trials using LIPUS 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.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in **Table 1**.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Unpublished			
NCT03382483[a]	A Prospective, Patient-centric, Observational, Consecutive Enrollment, Non-interventional Study of Patients At Risk for Fracture Non-union Treated with EXOGEN Compared to a National Healthcare Claims Database Control	12,387	May 2022 (unknown status; Last

NCT No.	Trial Name	Planned Enrollment	Completion Date
			Update Posted, Feb 2021)

NCT: national clinical trial

[a] denotes an industry-sponsored trial

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion 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.

National Institute for Health and Care Excellence

In 2013, the NICE published guidance on Exogen for the treatment of long-bone fractures with nonunion and delayed fracture healing.[32] 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 three 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 three and nine 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.[32] 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.

In 2018, NICE published guidance on the use of LIPUS in three clinical circumstances. The guidance made the following conclusions:

- To promote healing of fresh fractures at low risk of non-healing: "Current evidence does not show efficacy. Therefore, this procedure should not be used for this indication."[33]
- To promote healing of fresh fractures at high-risk of non-healing: "Current evidence on efficacy is very limited in quantity and quality. Therefore, this procedure should only be used in the context of research."[34]
- To promote healing of delayed and nonunion fractures: "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."[35]

American Academy of Orthopaedic Surgeons

In 2020, the American Academy of Orthopaedic Surgeons published updated guidelines on the treatment of distal radius fractures.[36] Although the Academy issued a limited recommendation for the use of LIPUS for adjuvant treatment of distal radius fractures in its prior 2009 guidelines, LIPUS was not mentioned in the updated guidelines.

Similarly, a 2021 AAOS guideline on management of hip fracture in older adults does not mention low-intensity pulsed ultrasound.[37]

In 2022, the AAOS published a guideline on the treatment of clavicle fractures.[37] The guideline includes a moderately strong recommendation that low-intensity pulsed ultrasound should not be used for acute mid-shaft clavicle fracture, based on a lack of data supporting its efficacy for accelerated healing or improved non-union rates. The only randomized trial that was available at the time of guideline development showed no difference in these outcomes compared to placebo. This 2022 guideline for the treatment of isolated clavicle fractures was developed with input from representatives from the American Shoulder and Elbow Surgeons, the Orthopaedic Trauma Association, and the American Society of Shoulder and Elbow Therapists.[38]

Medicare National Coverage

Effective 2001, ultrasonic osteogenic stimulators were covered as medically reasonable and necessary for the treatment of nonunion fractures.[39] 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. There were no changes made to this coverage decision during the last review in June 2005.

Regulatory Status

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 I 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: LOF.

Table 2 summarizes the FDA cleared or approved LIPUS devices.

Table 2. US 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) 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	Bioventus	1994;2000	P900009; P900009/ S006

Device	Indication	Manufacturer	Date Approved	PMA No./ Device Code
	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) [b] A nonunion is considered to be established when the fracture site shows no visibly progressive signs of healing.

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History

Date	Comments
06/01/19	New policy number, approved May 7, 2019. Policy 1.01.531 replaces policy 1.01.05 which is now deleted. Policy created with literature review through February 2019. Investigational policy statement regarding all other applications of low intensity pulsed ultrasound no longer contains the “including but not limited to” list of conditions.
04/01/20	New policy number (1.01.05), approved March 19, 2020, effective April 1, 2020. Policy 1.01.05 replaces policy 1.01.531 which is now deleted. Policy statements remain unchanged; this is effectively a policy renumber.
06/01/20	Annual Review, approved May 5, 2020. Policy updated with literature review through January 2020; references updated. Policy statements unchanged. Title changed from “Ultrasound Accelerated Fracture Healing Device” to "Low Intensity Pulsed Ultrasound Fracture Healing Device" to more accurately reflect the expanded labeled indications as per the Regulatory Status section.

Date	Comments
06/01/21	Annual Review, approved May 4, 2021. Policy updated with literature review through February 18, 2021; references added. Slightly revised practice guidelines section for clarity. Policy statements unchanged.
06/02/21	Updated Related Policies; removed 7.01.571 as it has been deleted.
06/01/22	Policy renumbered from 1.01.05 Low Intensity Pulsed Ultrasound Fracture Healing Device to 1.01.537 Low Intensity Pulsed Ultrasound Fracture Healing Device, approved May 10, 2022. Policy updated with literature review through February 3, 2022; no references added. Policy statements unchanged.
06/01/23	Annual Review, approved May 5, 2023. Policy updated with literature review through January 17, 2023; references added. Policy statement unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
06/01/24	Annual Review, approved May 13, 2024. Policy updated with literature review through January 17, 2024; references added. Policy statements unchanged.
07/01/25	Annual Review, approved June 23, 2025. Policy updated with literature review through January 30, 2025; references added. Policy statements unchanged.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.