

POLICY TITLE	LOW INTENSITY PULSED ULTRASOUND FRACTURE HEALING DEVICE
POLICY NUMBER	MP 6.021

CLINICAL BENEFIT	<input type="checkbox"/> MINIMIZE SAFETY RISK OR CONCERN. <input checked="" type="checkbox"/> MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. <input type="checkbox"/> ASSURE APPROPRIATE LEVEL OF CARE. <input type="checkbox"/> ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. <input type="checkbox"/> ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. <input type="checkbox"/> ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective date:	6/1/2026

POLICY

Low-intensity pulsed ultrasound is considered **investigational** for treatment of the following:

- Fresh fractures (surgically managed or non-surgically managed).
- Fracture nonunion and delayed union fractures.
- Stress fractures, osteotomy, and distraction osteogenesis.

There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with these procedures.

Policy Guidelines

Fresh (acute) fracture

There is no standard definition for 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, 1 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 used in U.S. 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 evidence review **MP 1.024**):

- 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 nonweight bearing.

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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.

Cross-References:

MP 1.024 Electrical Bone Growth Stimulation of the Appendicular Skeleton

MP 1.150 Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures

PRODUCT VARIATIONS

This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: <https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies>

DESCRIPTION/BACKGROUND

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.

Bone Fractures

An estimated 178 million new fractures were reported worldwide in 2019. Most bone fractures heal spontaneously over the course of 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 (e.g., smoking, diabetes, systemic disease).

Fracture Nonunion

There is no standard definition of a fracture nonunion. The 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,

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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 (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.

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. Food and Drug Administration product code: LOF.

RATIONALE

Summary of Evidence

For individuals who have fresh fractures (surgically or non-surgically 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 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 effect. The evidence is insufficient to determine the effects of the technology on health outcomes.

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,

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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 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.

DEFINITIONS

NA

DISCLAIMER

Capital Blue Cross' medical policies are used to determine coverage for specific medical technologies, procedures, equipment, and services. These medical policies do not constitute medical advice and are subject to change as permitted by law or applicable clinical evidence from independent treatment guidelines. Treating providers are solely responsible for medical advice and treatment of members. These policies are not a guarantee of coverage or payment. Payment of claims is subject to a determination regarding the member's benefit program and eligibility on the date of service, and a determination that the services are medically necessary and appropriate. Final processing of a claim is based upon the terms of contract that applies to the members' benefit program, including benefit limitations and exclusions. If a provider or a member has a question concerning this medical policy, please contact Capital Blue Cross' Provider Services or Member Services.

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CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Low-intensity pulsed ultrasound is considered Investigational: therefore, not covered:

Procedure Codes								
20979	E0760							

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POLICY HISTORY

MP 6.021	06/26/2020 Consensus Review. No change to policy statements, references updated.
	03/11/2021 Consensus Review. No change to policy statement. References updated.
	04/20/2022 Consensus Review. No change to policy statement. Coding table format updated. References reviewed and updated.
	03/29/2023 Consensus Review. No change to policy statements. Background and rationale updated. References reviewed and updated. Coding reviewed.

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	06/04/2024 Consensus Review. No change to policy statement. References reviewed and updated. No coding changes.
	04/10/2025 Consensus Review. No change to policy statement intent, NMN language changed to investigational. References reviewed and updated. No coding changes.
	09/03/2025 Administrative Update. Removed Benefit Variations Section and updated Disclaimer.
	02/20/2026 Consensus Review. No changes to policy statement. Updated policy formatting, guidelines, product variations, background, rationale, and references. No coding changes.

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