Policy Number	**DME101.030**
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Ultrasonic Osteogenesis Stimulator

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Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

An ultrasonic osteogenesis stimulator **may be considered medically necessary** when ALL of the following criteria are met:

- Nonunion of a fracture documented by a minimum of two sets of radiographs obtained prior to starting treatment with the osteogenesis stimulator, separated by a minimum of 90 days (see **NOTE 1**); and
- The fracture is not of the skull or vertebrae; and
- The fracture is not tumor related.

NOTE 1: Each radiograph set must include multiple views of the fracture site accompanied by a written interpretation by a treating practitioner stating that there has been no clinically significant evidence of fracture healing between the two sets of radiographs

An ultrasonic osteogenesis stimulator **is considered not medically necessary** when criteria above are not met, including use in the treatment of a fresh fracture or delayed union.

An ultrasonic osteogenesis stimulator **is considered not medically necessary** if it is used with other noninvasive osteogenesis stimulators.

Policy Guidelines

None.

Description

Ultrasonic osteogenesis stimulation 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. Ultrasonic osteogenesis stimulation 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. (2) 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. (3) 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). (3)

Treatment
Ultrasonic osteogenesis stimulation has been proposed to accelerate healing of fractures. It 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 the treatment 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.

Ultrasonic osteogenesis stimulation 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 U.S. Food and Drug Administration (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.

Rationale

This policy is based on a review of coverage guidance from the Centers for Medicare and Medicaid Services (CMS) specific to ultrasonic osteogenesis stimulators. (1)

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	20979
HCPCS Codes	E0760

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

References

Local Coverage Determination

1. Centers for Medicare and Medicaid Services. Local Coverage Determination for Osteogenesis Stimulators (L33796) Revision 8. Available at <https://www.cms.gov> (accessed September 11, 2025).

Other

2. Wu AM, Bisignano C, James SL, et al. Global, regional, and national burden of bone fractures in 204 countries and territories, 1990-2019: a systematic analysis from the Global Burden of Disease Study 2019. Lancet Healthy Longev. Sep 2021; 2(9):e580-e592. PMID 34723233
3. Buza JA, Einhorn T. Bone healing in 2016. Clin Cases Miner Bone Metab. 2016; 13(2):101-105. PMID 27920804

Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been changed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision	
Date	**Description of Change**
01/01/2026	Document updated. Coverage criteria revised to be consistent with coverage guidance from the Centers for Medicare and Medicaid Services. Added reference 1; others removed. Title changed from "Low Intensity Pulsed Ultrasound Fracture Healing Device."
01/01/2025	Document updated with literature review. Coverage unchanged. Added references 1, 3, 18, 23, 25, 30, and 34.
08/15/2023	Reviewed. No changes.
05/15/2022	Document updated with literature review. Coverage unchanged. Reference 28 added and 32 updated; others removed.
05/15/2021	Reviewed. No changes.
11/15/2020	Document updated with literature review. Coverage unchanged. Added references 18, 21, 24, 28-30. Title changed from: Ultrasound Accelerated Fracture Healing Device.
07/01/2019	Reviewed. No changes.
08/15/2018	Document updated with literature review. Coverage unchanged. Added references 1-2, 11, 15-18, 20, 27. Document title changed from: Low Intensity Ultrasound Accelerated Fracture Healing Device.
12/01/2017	Reviewed. No changes.
11/01/2016	Document updated with literature review. The following criteria: "who are at high risk (see NOTE #1) for delayed fracture healing or nonunion" was added to the following coverage statement: "Low-intensity ultrasound treatment may be considered medically necessary when used as an adjunct to conventional management (i.e., closed reduction and cast immobilization) for the treatment of fresh (<14 days) , closed fractures in skeletally mature individuals." In addition Note #1 was added to the coverage section noting the following: "Candidates for ultrasound treatment are those at high risk for delayed fracture healing or nonunion. These high risk factors may include either patient comorbidities or locations of fractures and include the following: diabetes, steroid therapy, osteoporosis, history of alcoholism, history of smoking, jones fracture, fracture of navicular bone in the wrist (also called the scaphoid), fracture of metatarsal, and factures associated

	with extensive soft tissue or vascular damage." The condition of "fresh surgically treated closed fractures" was added to the listing of the experimental, investigational and/or unproven coverage statement.
01/01/2015	Reviewed; no changes
03/15/2013	Document updated with literature review. The following was added: 1) Low-intensity ultrasound treatment may be considered medically necessary as a treatment of delayed union of bones, excluding the skull and vertebra. NOTE: Delayed union is defined as a decelerating healing process as determined by serial x-rays, 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. 2) Arthrodesis or failed arthrodesis added as examples of experimental, investigational and unproven indications.
07/01/2011	Document updated with literature review. No change in coverage. Stress fracture added as example of experimental, investigational and unproven indications. Rationale completely revised. Title changed to Low Intensity Ultrasound Accelerated Fracture Healing Device.
06/01/2009	Coverage revised
04/15/2008	Revised/updated entire document
11/01/2000	Revised/updated entire document
03/01/2000	Revised/updated entire document
04/01/1999	Revised/updated entire document
02/01/1997	Revised/updated entire document
04/01/1996	New medical document