



MASSACHUSETTS

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Medical Policy

Ultrasound Accelerated Fracture Healing Device

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Policy Number: 497

BCBSA Reference Number: 1.01.05

NCD/LCD: Local Coverage Determination (LCD): Osteogenesis Stimulators (L33796)

Related Policies

- Bone Morphogenetic Protein, #[097](#)
- Electrical Bone Growth Stimulation of the Appendicular Skeleton, #[499](#)
- Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures, #[498](#)

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Low-intensity pulsed ultrasound may be considered **NOT MEDICALLY NECESSARY** as a treatment of fresh fractures (surgically managed or nonsurgically managed).

Low-intensity pulsed ultrasound may be considered **NOT MEDICALLY NECESSARY** as a treatment of fracture nonunion and delayed union fractures.

Low-intensity pulsed ultrasound may be considered **NOT MEDICALLY NECESSARY** as a treatment of stress fractures, osteotomy, and distraction osteogenesis.

Medicare HMO BlueSM and Medicare PPO BlueSM Members

Medical necessity criteria and coding guidance for **Medicare Advantage members living in Massachusetts** can be found through the link(s) below.

[Local Coverage Determinations \(LCDs\) for National Government Services, Inc.](#)

Local Coverage Determination (LCD): Osteogenesis Stimulators (L33796)

Note: To review the specific LCD, please remember to click “accept” on the CMS licensing agreement at the bottom of the CMS webpage.

For medical necessity criteria and coding guidance for **Medicare Advantage members living outside of Massachusetts**, please see the Centers for Medicare and Medicaid Services website at <https://www.cms.gov> for information regarding your specific jurisdiction.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	This is not a covered service.
Commercial PPO and Indemnity	This is not a covered service.
Medicare HMO BlueSM	Prior authorization is not required .
Medicare PPO BlueSM	Prior authorization is not required .

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The following CPT and HCPCS codes are considered not medically necessary for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

CPT Codes

CPT codes:	Code Description
20979	Low intensity ultrasound stimulation to aid bone healing, noninvasive (nonoperative)

HCPCS Codes

HCPCS codes:	Code Description
E0760	Osteogenesis stimulator, low-intensity ultrasound, non-invasive

Description

Bone Fractures

An estimated 7.9 million fractures occur annually in the United States. 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.¹ 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).¹

Fracture Nonunion

There is no standard definition of a fracture nonunion.² The Food and Drug Administration 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

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, usually for 5 months.

Summary

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.

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. The evidence base has recently 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 of LIPUS; 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 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 only lower quality studies consisting of a small systematic review in scaphoid nonunions, a meta-analysis of nonunion in various locations, two low-quality RCTs, and one observational comparative study. The relevant outcomes are symptoms, morbid events, functional outcomes, and quality of life. Of the two 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 LIPUS and surgery, although the retrospective nature of the study, limits meaningful interpretation of these results. Additionally, the evidence base on the use of LIPUS in the management of fresh fractures has evolved as described above, and there is no demonstrated physiologic mechanism suggesting differential results of LIPUS in fracture nonunion or delayed union. The evidence is insufficient to determine the effects of the technology on health outcomes.

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 and one meta-analysis for distraction osteogenesis. The 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 three trials using LIPUS for distraction osteogenesis reported no statistically significant differences in physiological or functional outcomes. Additionally, the evidence base on the use of LIPUS in the management of fresh fractures has evolved as described above and there is no demonstrated physiologic mechanism suggesting differential results of LIPUS in stress fractures, osteotomy sites, or distraction osteogenesis. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy History

Date	Action
4/2019	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
4/2019	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
4/2018	New references added from BCBSA National medical policy. Summary clarified.
2/2018	BCBSA National medical policy review. The following indications were changed from medically necessary to not medically necessary: fresh fractures (surgically and nonsurgically managed) and nonunion/delayed union fractures. Clarified coding information. Effective 2/1/2018.
10/2016	New references added from BCBSA National medical policy.
10/2016	Coding information clarified.
3/2015	New references added from BCBSA National medical policy.
7/2014	Updated Coding section with ICD10 procedure and diagnosis codes. Effective 10/2015.
6/2014	BCBSA National medical policy review. New investigational indications described; medically necessary indications clarified. Effective 6/1/2014.
12/2013	Added LCD: L11501 to the policy
4/2013	BCBSA National medical policy review. New investigational indications described. Effective 4/1/2013.
2/2013	Ultrasound Accelerated Fracture Healing Device transferred to medical policy #497.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
6/2011	Reviewed - Medical Policy Group - Orthopedics, Rehabilitation Medicine and Rheumatology. No changes to policy statements.
4/2011	BCBSA National medical policy review. No changes to policy statements.
7/2010	Reviewed - Medical Policy Group - Orthopedics, Rehabilitation Medicine and Rheumatology. No changes to policy statements.
12/2009	BCBSA National medical policy review. Changes to policy statements.
7/2009	Reviewed - Medical Policy Group - Orthopedics, Rehabilitation Medicine and Rheumatology. No changes to policy statements.
7/2008	Reviewed - Medical Policy Group - Orthopedics, Rehabilitation Medicine and Rheumatology. No changes to policy statements.
4/2008	BCBSA National medical policy review. No changes to policy statements.
2/2008	BCBSA National medical policy review. Changes to policy statements.
7/2007	Reviewed - Medical Policy Group - Orthopedics, Rehabilitation Medicine and Rheumatology. No changes to policy statements.
6/2007	BCBSA National medical policy review. Changes to policy statements.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

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