



# 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 (For Plan internal use only)

#### 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 is considered [INVESTIGATIONAL](#) as a treatment of fresh fractures (surgically managed or nonsurgically managed).

Low-intensity pulsed ultrasound is considered [INVESTIGATIONAL](#) as a treatment of fracture nonunion and delayed union fractures.

Low-intensity pulsed ultrasound is considered [INVESTIGATIONAL](#) as a treatment of stress fractures, osteotomy, and distraction osteogenesis.

#### 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 <b>not</b> a covered service.
Commercial PPO and Indemnity	This is <b>not</b> a covered service.

#### 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 investigational for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:**

### **CPT Codes**

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

### **HCPCS Codes**

<b>HCPCS codes:</b>	<b>Code Description</b>
E0760	Osteogenesis stimulator, low-intensity ultrasound, non-invasive

## **Description**

### **Bone Fractures**

An estimated 178 million new fractures were reported worldwide in 2019.<sup>1</sup> 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.<sup>2</sup> 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).<sup>2</sup>

### **Fracture Nonunion**

There is no standard definition of a fracture nonunion.<sup>3</sup> 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.

## Summary

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.

## Policy History

Date	Action
5/2024	Annual policy review. References updated. Policy statements unchanged.
5/2023	Annual policy review. Description, summary and references updated. Policy statements unchanged.
5/2022	Annual policy review. Description, summary and references updated. Not medically necessary policy statements updated to investigational for policy standardization purposes. Policy intent unchanged.
4/2021	Annual policy review. References updated. Policy statements unchanged.

1/2021	Medicare information removed. See MP #132 Medicare Advantage Management for local coverage determination and national coverage determination reference.
5/2020	Annual policy review. Description, summary and references updated. Policy statements unchanged.
4/2019	Annual policy review. Description, summary and references updated. Policy statements unchanged.
4/2018	Annual policy review. Summary clarified.
2/2018	Annual 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	Annual policy review. New references added.
10/2016	Coding information clarified.
3/2015	Annual policy review. New references added.
7/2014	Updated Coding section with ICD10 procedure and diagnosis codes. Effective 10/2015.
6/2014	Annual policy review. New investigational indications described; medically necessary indications clarified. Effective 6/1/2014.
4/2013	Annual 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.

## Information Pertaining to All Blue Cross Blue Shield Medical Policies

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

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

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