

## FEP 1.01.05 Ultrasound Accelerated Fracture Healing Device

**Effective Date:** July 15, 2018

**Related Policies:**

7.01.07 Electrical Bone Growth Stimulation of the Appendicular Skeleton  
7.01.85 Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures

## Ultrasound Accelerated Fracture Healing Device

### 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.

### FDA REGULATORY STATUS

In 1994, the Sonic Accelerated Fracture Healing System (SAFHS®; renamed Exogen 2000® and since 2006, Exogen 4000+; Bioventus) was approved by the U.S. Food and Drug Administration 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. Food and Drug Administration product code: LPQ.

### POLICY STATEMENT

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.

### 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 (Heckman et al, 1994; Kristiansen et al, 1997; Emami et al, 1999), but there is definitional variability. For example, 1 study defined fresh as less than 5 days after fracture (eg, Lubbert et al, 2008), while another defined fresh as up to 10 days postfracture (Mayr et al. [Does low intensity,

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pulsed ultrasound speed healing of scaphoid fractures?) [German]. *Handchir Mikrochir Plast Chir*. Mar 2000;32(2):115-122). Most fresh closed fractures heal without complications using of standard fracture care (ie, closed reduction and cast immobilization).

### NONUNION

There is no consensus on the definition of nonunions. One definition is a failure of progression of fracture healing for at least 3 consecutive months (and at least 6 months postfracture) accompanied by clinical symptoms of delayed/nonunion (pain, difficulty weight bearing; Buza & Einhorn, 2016).

The definition of nonunion used in U.S. Food and Drug Administration 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 patient selection criteria are consistent with those proposed for electrical stimulation as a treatment of nonunions (see evidence review 7.01.07):

- 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 patient can be adequately immobilized and, based on age, is likely to comply with nonweight bearing.

### 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.

### BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

### RATIONALE

#### 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 RCTs and several meta-analyses. 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, 3 low-quality RCTs, and observational studies. Relevant outcomes are symptoms, morbid events, functional outcomes, and quality of life. Reported outcomes in this subgroup of fractures do not include functional outcomes. A wide range of healing rates has been reported across the observational studies with a lack of comparison with routine surgical care, limiting any 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

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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. 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. 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.

### SUPPLEMENTAL INFORMATION

#### Practice Guidelines and Position Statements

##### **British Medical Journal Rapid Recommendation**

The *British Medical Journal* (BMJ) Rapid Recommendations are a series of articles, produced by BMJ in collaboration with the MAGIC group,<sup>29</sup> to provide clinicians with practice guidelines. In 2017, BMJ Rapid Recommendations published guidelines on the use of low-intensity pulsed ultrasound (LIPUS) for bone healing.<sup>30</sup> The guidelines were based on a 2017 systematic review, which included 26 randomized controlled trials evaluating patients with fresh fractures not surgically managed, fresh fractures surgically managed, nonunion fractures, osteotomy, and distraction osteogenesis.<sup>3</sup> The committee concluded that there is “moderate to high certainty evidence to support a strong recommendation against the use of LIPUS for bone healing.” Furthermore, the guideline expert panel discussed whether the results of higher quality studies in patients with fresh fractures reported in Schandelmaier et al (2017) would apply to other types of fractures including nonunions and osteotomies.<sup>3</sup> “After extensive deliberations, the panel found no compelling anatomical or physiological reasons why LIPUS would probably be beneficial in these other patient populations.”<sup>30</sup>

##### **National Institute for Health and Care Excellence**

The National Institute for Health and Care Excellence (NICE) published guidance (2010) on LIPUS to promote fracture healing.<sup>31</sup> NICE concluded that this procedure “can reduce fracture healing” and is particularly beneficial for “delayed healing and fracture non-union.”

NICE published guidance (2013) on Exogen for the treatment of long-bone fractures with nonunion and delayed fracture healing.<sup>32</sup> 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 3 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 3 and 9 months after fracture” and need for surgery, “cost consequences” were uncertain. The next review of this guidance is in 2018.

##### **American Academy of Orthopaedic Surgeons**

The American Academy of Orthopaedic Surgeons (2009) published guidelines on the treatment of distal radius fractures.<sup>33</sup> The Academy issued a limited recommendation for the use of LIPUS for adjuvant treatment of distal radius fractures. While evidence from 1 study demonstrated an increased rate of healing (measured by the absence of pain and radiographic union), the additional cost of LIPUS resulted in a “limited” recommendation.

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### U.S. Preventive Services Task Force Recommendations

Not applicable.

### Medicare National Coverage

Effective 2001, ultrasonic osteogenic stimulators were covered as medically reasonable and necessary for the treatment of nonunion fractures.<sup>34</sup> 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.

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### POLICY HISTORY

Date	Action	Description
March 2012	New	
December 2012	Updated Policy	Policy rationale and references updated; arthrodesis added to investigational statement; definition of delayed unions revised to 3 months for consistency with definition of nonunion.
March 2014	Updated Policy	Policy updated with literature review. References 12, 16, and 18 added; clarification of non-union of previously surgically-treated fractures; fresh surgically-treated closed fractures added to Investigational statement.
March 2015	Updated Policy	Policy updated with literature review; references 11 and 20 added. Information added to Policy Guidelines to clarify definition of "fresh fracture". Policy statements unchanged.
December 2016	Updated Policy	Policy updated with literature review through July 1, 2016; references 14 and 16 added. Policy statements unchanged.
September 2017	Updated Policy	Policy updated with literature review through January 25, 2017; references 3-4, 7, 17, and 25-26 were added. The following indications were changed from medically necessary to not medically necessary: fresh fractures (surgically and nonsurgically managed) and nonunion/delayed union fractures.

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June 2018	Updated Policy	Policy updated with literature review through January 8, 2018; references 5-6 and 16-17 added. Policy statements are unchanged.
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