FEP Medical Policy Manual

FEP 1.01.05 Ultrasound Accelerated Fracture Healing Device

Effective Policy Date: July 1, 2019
Original Policy Date: March 2012

Related Policies:
7.01.07 - Electrical Bone Growth Stimulation of the Appendicular Skeleton
7.01.85 - Bone Morphogenetic Protein

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.

OBJECTIVE

The objective of this evidence review is to evaluate whether, compared with routine care without low-intensity pulsed ultrasound, low-intensity pulsed ultrasound improves the net health outcome when used as an adjunct to routine care to treat fractures (including fresh fractures, surgically treated closed fractures, delayed unions, nonunions, stress fractures, osteotomy sites, and distraction osteogenesis).

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.

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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 post-fracture (Mayer et al. [Does low intensity, 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 post-fracture) 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 7.91.07):

- 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).

The transducer used for ultrasound treatment is categorized as durable medical equipment.

**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.

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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. The relevant outcomes are symptoms, morbidity events, functional outcomes, and QOL. 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, morbidity events, functional outcomes, and QOL. 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, though 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, morbidity events, functional outcomes, and QOL. 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.

Supplemental Information

Practice Guidelines and Position Statements

British Medical Journal Rapid Recommendation

The BMJ Rapid Recommendations are a series of articles, produced by BMJ in collaboration with the MAGIC group, to provide clinicians with practice guidelines. BMJ Rapid Recommendations (2017) published guidelines on the use of low-intensity pulsed ultrasound (LIPUS) for bone healing. 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. 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 SchandeMaier et al (2017) would apply to other types of fractures including nonunions and osteotomies. After extensive deliberations, the panel found no compelling anatomical or physiological reasons why LIPUS would probably be beneficial in these other patient populations.

National Institute for Health and Care Excellence

The NICE(2018) published a guidance on the use of LIPUS to promote healing of fresh fractures at low-risk of non-healing. The guidance states that the “current evidence does not show efficacy. Therefore, this procedure should not be used for this indication.”

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The NICE (2018) published a guidance on the use of LIUPUS to promote healing of fresh fractures at high-risk of non-healing. The guidance states that the "current evidence on efficacy is very limited in quantity and quality. Therefore, this procedure should only be used in the context of research."

The NICE (2018) published a guidance on the use of LIUPUS to promote healing of delayed and nonunion fractures. The guidance states that the "current evidence on efficacy is inadequate in quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research."

The NICE (2013) published guidance on Exogen for the treatment of long-bone fractures with nonunion and delayed fracture healing. The 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 three 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. The Academy issued a limited recommendation for the use of LIUPUS for adjuvant treatment of distal radius fractures. While evidence from one study demonstrated an increased rate of healing (measured by the absence of pain and radiographic union), the additional cost of LIUPUS resulted in a "limited" recommendation.

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. 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.

REFERENCES


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### POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

<table>
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<tr>
<th>Date</th>
<th>Action</th>
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<td>March 2012</td>
<td>New policy</td>
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<tr>
<td>December 2012</td>
<td>Replace policy</td>
<td>Policy rationale and references updated; arthrodesis added to investigational statement; definition of delayed unions revised to 3 months for consistency with definition of nonunion.</td>
</tr>
<tr>
<td>March 2014</td>
<td>Replace policy</td>
<td>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.</td>
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<tr>
<td>March 2015</td>
<td>Replace policy</td>
<td>Policy updated with literature review; references 11 and 20 added. Information added to Policy Guidelines to clarify definition of “fresh fracture”. Policy statements unchanged.</td>
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<tr>
<td>December 2016</td>
<td>Replace policy</td>
<td>Policy updated with literature review through July 1, 2016; references 14 and 16 added. Policy statements unchanged.</td>
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<tr>
<td>September 2017</td>
<td>Replace policy</td>
<td>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.</td>
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<td>June 2018</td>
<td>Replace policy</td>
<td>Policy updated with literature review through January 8, 2018; references 5-6 and 16-17 added. Policy statements are unchanged.</td>
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