MEDICAL POLICY – 1.01.531
Ultrasound Accelerated Fracture Healing Device

BCBSA Ref. Policy: 1.01.05
Effective Date: June 1, 2019
Last Revised: May 7, 2019
Replaces: 1.01.05

RELATED MEDICAL POLICIES:
2.01.40 Extracorporeal Shock Wave Treatment for Plantar Fasciitis and Other Musculoskeletal Conditions
7.01.07 Electrical Bone Growth Stimulation of the Appendicular Skeleton
7.01.571 Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

Introduction

Ultrasound is a sound wave that humans can’t hear. Ultrasound has been tried to help broken bones heal. It was believed that ultrasound stimulates growth of new bone by activating the growth of new bone cells. The latest large studies, however, show there isn’t enough evidence to conclude that ultrasound waves help bones heal. Using ultrasound on bones that were cut during surgery or broken is not medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low-intensity pulsed ultrasound</td>
<td>Low-intensity pulsed ultrasound is considered not medically necessary for</td>
</tr>
</tbody>
</table>
<pre><code>                               | the treatment of the following:                                          |
</code></pre>
### Treatment and Medical Necessity

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Fresh fractures (surgically managed or nonsurgically managed)</td>
<td></td>
</tr>
<tr>
<td>• Fracture nonunion and delayed union fractures</td>
<td></td>
</tr>
<tr>
<td>• Stress fractures, osteotomy and distraction osteogenesis</td>
<td></td>
</tr>
</tbody>
</table>

**Note:** See Definition of Terms for more information.

### Treatment and Investigational

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other applications of low-intensity pulsed ultrasound treatment</td>
<td>All other applications of low-intensity pulsed ultrasound treatment not listed in this policy are considered investigational.</td>
</tr>
</tbody>
</table>

### Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td>Low intensity ultrasound stimulation to aid bone healing, noninvasive (nonoperative)</td>
</tr>
<tr>
<td>E0760</td>
<td>Osteogenesis stimulator, low intensity ultrasound, non-invasive</td>
</tr>
</tbody>
</table>

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### Related Information

**Definition of Terms**

**Fresh (acute) fracture:** There is no standard definition of 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 (Lubbert et al, 2008), while another defined fresh as up to

**Delayed union:** This 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.

**Jones fracture:** This is a transverse stress fracture of the base of the little toe or fifth metatarsal of the foot.

**Nonunion:** There is no consensus on the definition of nonunion. 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 in the 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 Related Policies):

- 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 non-weight bearing

**Note:** Electrical bone growth stimulation for healing is covered in a separate medical policy (see Related Policies).
Benefit Application

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

Evidence Review

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.

Background

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 of Evidence**

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 effect. 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, 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, 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.

**Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this review is listed in Table 1.
Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02383160a</td>
<td>A Randomized Controlled Trial Comparing Low-Intensity, Pulsed Ultrasound to Placebo in the Treatment of Operatively Managed Scaphoid Non-unions</td>
<td>154</td>
<td>Dec 2018 (unknown status)</td>
</tr>
<tr>
<td>NCT03382483a</td>
<td>Observational, Non-Interventional Use of LIPUS to Mitigate Fracture Non-Union in Patients at Risk (BONES)</td>
<td>3000</td>
<td>Dec 2019</td>
</tr>
</tbody>
</table>

NCT: national clinical trial

*a* denotes an industry-sponsored trial

**Clinical Input Received From Physician Specialty Societies and Academic Medical Centers**

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

**2012 Input**

In response to requests, input was received from 4 academic medical centers while this policy was under review in 2012. Input supported the use of low-intensity pulsed ultrasound for delayed unions and nonunions of bones excluding the skull and vertebra, and in fresh closed fractures at high risk for delayed fracture healing or nonunion. Commentators agreed that other applications of low-intensity pulsed ultrasound treatment are investigational, including, but not limited to, treatment of congenital pseudoarthroses, open fractures, stress fractures, arthrodesis, or failed arthrodesis. Additional risk factors were noted, including use of anticoagulants, immunosuppressive drugs or chemotherapy, infection at the fracture site, severe anemia, obesity, and fracture locations more prone to nonunion such as tibial and distal radial fractures.
2011 Input

In response to requests, input was received from 2 physician specialty societies and 1 academic medical center while this policy was under review in 2011. Input supported the use of ultrasound for nonunion and for fresh closed fractures at high risk for delayed fracture healing or nonunion as described in the policy. One reviewer supported including chemotherapy, immunosuppressive agents, history of infection, Charcot neuroarthropathy, and fractures of the tibial shaft or clavicle as additional risk factors, and another supported including fractures of the talus and sesamoids as additional risk factors.

2008 Input

In response to requests, input was received from 1 physician specialty society while this policy was under review in 2008. Input obtained through the American Academy of Orthopaedic Surgeons supported the positions on the criteria for medical necessity and the conditions considered investigational (eg, delayed union and open/unstable grade II or III fractures).

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,28 to provide clinicians with practice guidelines. BMJ Rapid Recommendations (2017) published guidelines on the use of low-intensity pulsed ultrasound (LIPUS) for bone healing.29 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.3 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.3 “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 National Institute for Health and Care Excellence (NICE) (2018) published a guidance on the use of LIPUS to promote 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."

The NICE (2018) published a guidance on the use of LIPUS 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 LIPUS 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 governances, consent and audit or research."

NICE (2013) published guidance on Exogen for the treatment of long-bone fractures with nonunion and delayed fracture healing. 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. The Academy issued a limited recommendation for the use of LIPUS 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 LIPUS, resulted in a “limited” recommendation.

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.

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.

References


### History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>06/01/19</td>
<td>New policy, approved May 7, 2019. This policy replaces 1.01.05. Policy created with literature review through February 2019. Investigational policy statement regarding all other applications of low intensity pulsed ultrasound no longer contains the “including but not limited to” list of conditions.</td>
</tr>
</tbody>
</table>

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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
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