MEDICAL POLICY – 1.01.05
Ultrasound Accelerated Fracture Healing Device

BCBSA Ref. Policy: 1.01.05

Effective Date: June 1, 2016*
Last Revised: Sept. 1, 2017
Replaces: N/A

*This policy has been revised.
Click here to view the upcoming changes.

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
7.01.85 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

 sélectionnez ce lien ci-dessous pour être redirigé vers la section suivante.

Introduction

Ultrasound is a sound wave that humans can’t hear. Ultrasound can be used to help broken bones heal. It’s believed that ultrasound stimulates growth of new bone. A probe, called a transducer, is set on the skin’s surface at the site of the break. The ultrasound waves travel through the skin and soft tissue. It’s thought that the ultrasound waves activate the growth of new bone cells. This treatment is used to help bones that are newly broken, have not healed for a long time (a non-union), or in cases where there is a risk of poor healing because of diabetes, smoking, or other medical reasons. The medical policy describes when low-intensity ultrasound treatment may be medically necessary for broken bones.

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.
<table>
<thead>
<tr>
<th>Treatment</th>
<th>Considered Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low-intensity ultrasound treatment</td>
<td>All other applications of low-intensity ultrasound treatment not listed in this policy are investigational, including, but not limited to, treatment of congenital pseudarthroses, open fractures, fresh surgically-treated closed fractures, stress fractures, arthrodesis or failed arthrodesis.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Medically Necessary Coverage Criteria</th>
</tr>
</thead>
</table>
| Low-intensity ultrasound treatment| Low-intensity ultrasound treatment may be considered medically necessary for the treatment of any of the following:  
  • Delayed union of bones, including delayed union of previously surgically-treated fractures, and excluding the skull and vertebra.  
  • Fracture nonunion of bones, including nonunion of previously surgically-treated fractures, and excluding the skull and vertebra.  
  • Fresh, closed fractures in skeletally mature individuals when used as an adjunct to conventional non-surgical management (i.e., closed reduction and cast immobilization). |

Note: See Definition of Terms for more information.

Candidates for ultrasound treatment are those at high risk for delayed fracture healing or nonunion. These risk factors may include either patient comorbidities or fracture locations.

**Patient comorbidities include the following:**  
- Diabetes  
- Steroid therapy  
- Osteoporosis  
- History of alcoholism  
- History of smoking

**High risk fracture locations include the following:**
## Treatment

<table>
<thead>
<tr>
<th>Medically Necessary Coverage Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Jones fracture</td>
</tr>
<tr>
<td>- Fracture of navicular bone in the wrist (also called the scaphoid)</td>
</tr>
<tr>
<td>- Fracture of metatarsal</td>
</tr>
<tr>
<td>- Fractures associated with extensive soft tissue or vascular damage</td>
</tr>
</tbody>
</table>

## Coding

<table>
<thead>
<tr>
<th>CPT</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>20979</td>
<td>Low intensity ultrasound stimulation to aid bone healing, noninvasive (nonoperative)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HCPCS</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E0760</td>
<td>Osteogenesis stimulator, low intensity ultrasound, non-invasive</td>
</tr>
</tbody>
</table>

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

## Related Information

### Definition of Terms

**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,\(^1\)\(^-\)\(^3\) but there is variability. For example, 1 study defined fresh as less than 5 days after fracture,\(^4\) while another defined fresh as up to 10 days after fracture.\(^5\) Most fresh closed fractures heal without complications with the use of standard fracture care, i.e., closed reduction and cast immobilization.

**Delayed union:** This is 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 not a consensus for the definition of nonunions. One proposed definition is failure of progression of fracture-healing for at least 3 consecutive months (and at least 6 months following the fracture) accompanied by clinical symptoms of delayed/nonunion (pain, difficulty weight bearing).

The definition of nonunion in the U.S. Food and Drug Administration (FDA) labeling suggests that nonunion is considered established when the fracture site shows no visibly progressive signs of healing, without giving any guidance regarding the timeframe of observation. However, it is suggested that a reasonable time period for lack of visible signs of healing is 3 months. The following patient selection criteria are consistent with those proposed for electrical stimulation as a treatment of non-unions (see Related Policies):

- At least 3 months have passed since the date of the fracture
- Serial radiographs have confirmed that no progressive signs of healing have occurred
- The fracture gap is 1 cm or less
- The patient can be adequately immobilized and is of an age when he/she 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 (DME).
The policy was initially developed in December 1995. Since that time, the policy has been updated on a regular basis using MEDLINE literature searches. The most recent literature review was conducted through April 18, 2016.

Description

Low-intensity pulsed ultrasound (US) has been investigated as a technique to accelerate healing of fresh fractures, delayed unions, and nonunions. US is delivered with the use of a transducer applied to the skin surface overlying the fracture site.

Background

Most bone fractures heal spontaneously over the course of several months following injury. However, approximately 5% to 10% of all fractures have delayed healing, resulting in continued morbidity and increased utilization of health care services. US may accelerate healing of fractures by stimulating new bone growth, and therefore, has been proposed as a treatment for fractures with delayed healing or at high risk for nonhealing.

The current policy does not limit the use of the device to specific fracture sites. Depending on their function, bones are composed of a varying combination of cortical and trabecular bone. However, at the cellular level, the type of bone cannot be distinguished histologically. The inclusion of all bones regardless of the anatomic site is based on this histologic similarity of all bones; it is not anticipated that the efficacy of US-accelerated healing would vary according to the anatomic site and function of the bone.

The definition of a fracture nonunion has remained controversial. For electrical bone growth stimulators (see Related Policies) labeling defined nonunion as follows: “A nonunion is considered to be established when a minimum of 9 months has elapsed since injury and the fracture site shows no visibly progressive signs of healing for minimum of 3 months.” Others have contended that 9 months represents an arbitrary cutoff point that does not reflect the complicated variables that are present in fractures, i.e., degree of soft tissue damage, alignment of the bone fragments, vascularity, and quality of the underlying bone stock. Other proposed definitions of nonunion involve 3 to 6 months’ time from original healing, or simply when serial
radiographs fail to show any further healing. According to FDA labeling for a low-intensity pulsed US device, “a nonunion is considered to be established when the fracture site shows no visibly progressive signs of healing.”

Delayed union is generally considered a failure to heal between 3 and 9 months after fracture, after which the fracture site would be considered to be a nonunion. 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.) Together, delayed union and nonunion are sometimes referred to as “ununited fractures.” To determine the status of fracture healing, it is important to include both radiographic and clinical criteria. Clinical criteria include the lack of ability to bear weight, fracture pain, and tenderness on palpation.

Ultrasound treatment can be self-administered with one daily 20-minute treatment, continuing until the fracture has healed. The mechanism of action at the cellular level is not precisely known but is thought to be related to a mechanical effect on cell micromotion/deformation, causing an increase in stimulation of transmembrane cell adhesion molecules and upregulation of cyclooxygenase-2.

**Fresh Fractures**

The policy regarding fresh fractures is based in part on a 1995 TEC Assessment that concluded that ultrasound (US) fracture healing met the TEC criteria for the indications labeled by the U.S. Food and Drug Administration (FDA) as a treatment of closed, fresh fractures of the tibial or distal radius (i.e., Colles’) fractures. Since the TEC Assessment, there have been numerous randomized controlled trials (RCTs) and systematic reviews of clinical trials on the use of US to improve healing in fresh fractures.

**Systematic Reviews**

A 2002 meta-analysis conducted by Busse et al. supported the use of low-intensity US as a technique for fractures treated nonoperatively. This systematic review was updated in 2009 and included RCTs of low-intensity pulsed ultrasonography for any type of fracture. Thirteen trials were included; in 5 of them, patients were managed conservatively, and in 8 studies, patients had US therapy after operative management (distraction osteogenesis in 3 studies, bone graft for nonunion in one, operative treatment of fresh fractures in 4). US therapy significantly
accelerated radiographic healing of fractures in all 3 RCTs of conservatively managed fresh fractures that assessed this outcome. (These trials are described in more detail next.)

The trials of operatively managed (open) fresh fractures outcomes were inconsistent; 4 trials provided low-quality evidence for acceleration of healing by US therapy. Pooled results of 2 trials showed a non-significant mean reduction in radiographic healing time of 16.6%.

A 2014 update of a Cochrane review on US and shockwave therapy included 12 studies on US; 8 of the studies were RCTs with placebo controls, 2 were RCTs without placebo controls, and 2 were quasi-randomized.10,11 The included studies were limited in methodologic quality, with all having some evidence of bias. There was very limited evidence on functional outcomes. Pooling results from eight studies (446 fractures) showed no significant reduction in time to union of complete fractures. This systematic review included studies of conservatively managed fractures along with surgically treated fractures and stress fractures. Subgroup analysis comparing conservatively and operatively treated fractures raised the possibility that pulsed US may be effective in reducing healing time in conservatively managed fractures, but a test for subgroup differences did not confirm a significant difference between the subgroups. The review concluded that while a potential benefit of US for acute fractures could not be ruled out, the currently available evidence was insufficient to support its routine use.

**RCTs of Closed Fractures**

In a 1997 multicenter RCT by Kristiansen et al, 60 patients with dorsally angulated fractures of the distal radius treated with manipulation and cast were randomly assigned to 10 weeks of daily treatment with a pulsed US device or an inactive device.2 All patients started US within 7 days after having sustained the fracture. Blinded radiographic and clinical examinations showed faster healing in the US group (61 days) than in the control group (98 days) (p<0.001). Each radiographic stage of healing also was significantly accelerated in the treatment group.

Heckman et al. (1994) performed a double-blind RCT comparing US treatment (n=33) with a placebo-control device (n=34) in closed or grade-I (clean, <1 cm puncture) open fractures of the tibial shaft.1 Treatment was started within 7 days after the fracture and consisted of one 20-minute period each day. Time-to-healing was 86 days in the treatment group versus 114 days in the control group (p=0.01), and time to overall (clinical and radiographic) healing was 96 days in the active-treatment group compared with 154 days in the control group (p<0.001).
Scaphoid fractures were treated with US in a 2008 study done in Germany. Fifteen patients with fresh scaphoid fractures (≤10 days) were randomly assigned to treatment and 15 to placebo device groups. Healing was assessed by computed tomography (CT) scans every 2 weeks. Fractures treated with US healed in 43.2 days versus 62 days in the control group (p<0.01). Pooled data from these studies demonstrated a mean reduction in radiographic healing time of 36.9% (95% confidence interval [CI], 25.6% to 46.0%).

Lubbert et al. performed a multicenter double-blind RCT of US treatment of fresh (<5 days) clavicle shaft fractures. Patients were taught to use US devices for 20 minutes each day for 28 days and to record daily their subjective feeling as to whether the fracture healed (the primary outcome measure), pain on visual analog scale (VAS), level of daily activities once a day expressed as hours of activity (work, household work, sport), and analgesic use. A total of 120 patients (61 active, 59 placebo) started study treatment. Nine patients in the active group and 10 in the placebo group were excluded from analysis because of incomplete follow-up or early withdrawal from the study. The day that the fracture clinically healed according to patient perception was determined in 92 patients (47 active, 45 placebo); mean duration of time to clinical healing was 26.77 days in the active group versus 27.09 days in the placebo group. Between-group differences in analgesic use and mean VAS were not significant.

**RCTs of Open Fractures and Surgically Treated Closed Fractures**

For the treatment of open fractures, data are conflicting regarding the efficacy of ultrasonic accelerated fracture healing systems, specifically for patients treated surgically with placement of an intramedullary nail. For example, Emami et al. (1999) randomly assigned 32 patients with a fresh tibial fracture that was fixed with an intramedullary rod to undergo additional treatment with an active or inactive US device. US treatment began within 3 days of surgery, and with 1 exception, within 7 days of injury. Time-to-healing was not significantly different in the 2 groups, and the authors concluded that there was no benefit in operatively treated fractures.

In contrast, Leung et al. (2004) randomly assigned 30 complex tibial fractures (in 28 patients) treated with internal or external fixation to receive or not receive additional treatment with low-intensity US. US treatment was begun when the patient’s condition had stabilized, and the open wound was covered with simple closure or skin grafts. The duration of tenderness, time to weight bearing, and time to callus formation were significantly less in those in the US group. Due to the inconsistent results in the 2 small randomized trials, and the negative results of the meta-analysis, low-intensity US is considered investigational for open fractures.
In 2011, Dijkman et al. reported data from a sub-study of 51 patients in a larger RCT that enrolled patients with open or closed tibial shaft fractures that were treated surgically with an intramedullary nail. According to www.ClinicalTrials.gov (NCT00667849), “the study was terminated due to futility,” suggesting lack of benefit for this indication.

Section Summary

There is some RCT evidence that US treatment improves radiographic healing for closed fresh fractures, but this finding is not consistent for studies of open fresh fractures. A 2009 systematic review and meta-analysis of RCTs found moderate- to very low-quality evidence for low-intensity pulsed ultrasonography in accelerating functional recovery among patients with fracture. The systematic review concluded that large trials of high methodologic quality focusing on patient-centered outcomes, such as quality of life and return to function, are needed to determine whether US fracture healing devices provide important benefits to patients. A 2014 Cochrane review that did not distinguish between closed and open fractures reported that there is a possibility that pulsed US may be effective in reducing healing time in conservatively managed fractures, but that currently available evidence was insufficient to support its routine use.

Nonunions

The policy regarding nonunion of fractures is based on data presented to FDA as part of the approval process for the Sonic Accelerated Fracture Healing System (SAFHS®) as a treatment of fracture nonunions. The following data were reported and are included in the package insert for the device:

- Data were collected on 74 cases of established nonunion with a mean fracture age of nearly 3 years. The principal outcome measure was the percentage of patients with healed nonunions, as determined clinically and by radiographic analysis. Each case served as its own control, based on the definition of nonunion that suggests that nonunions have a 0% probability of achieving a healed state without an intervention.

- A total of 64 (86%) of 74 cases were healed with use of low-intensity ultrasound. Time-to-healing was 173 days. The healed rate of scaphoid bones was lower, at 33% (2 of 6 cases),
which was partially responsible for a significant difference between the healing rates of long bones (92%) versus other bones (67%).

- Fracture age also affected healing rates, with fractures over 5 years old having a healing rate of 50% compared with a healing rate of 95% in those present for no more than 1 year.

A 2007 study used prospectively defined criteria for analysis of all Dutch patients (96 participating clinics) who had been treated with US for established nonunion of the tibia (characterized by a total stop of all fracture repair processes). Included in the analysis were 71 patients who were at least 3 months from the last surgical intervention and did not show any healing improvements in the 3 months before US treatment (average fracture age, 257 days; range, 180-781). All patients were followed up (average, 2.7 years) by questionnaire, or by phone, if needed. There was an overall healing rate of 73%, at an average 184 days to healing (range, 52-739). No difference in healing rate for open or closed fractures was observed.

**Delayed Union**

In 2010, Schofer et al. reported an industry-sponsored, multicenter, randomized, double-blinded, sham-controlled trial of low-intensity pulsed US in 101 patients with delayed union of the tibia. Delayed union was defined as lack of clinical and radiologic evidence of union, bony continuity, or bone reaction at the fracture site for no less than 16 weeks from the index injury or the most recent intervention. Roughly one-third of patients had an open fracture. Fifty-one patients were randomized to daily treatment with US, and 50 were randomized to an inactive sham device (20 minutes daily for 16 weeks). The primary outcome measure was change in bone mineral density (BMD) over the 16 weeks, assessed by CT attenuation coefficients, or Hounsfield units. Gap area at the fracture site was a secondary endpoint. The primary analysis was intention-to-treat with imputation of missing values (24% of sham-treated subjects and 9.8% of active-treated subjects were missing post-treatment values). Mean improvement in BMD was 34% (90% CI: 14% to 57%) greater for US-treated subjects compared with sham. Analysis of “completers” showed a medium effect size (0.53) of the treatment. A mean reduction in bone gap area also favored US treatment, with a mean change in log gap area of -0.131 mm² for active treatment and -0.097 mm² for sham (effect size, -0.47; 95% CI: -0.91 to -0.03). Untransformed data showed a difference between groups of -0.457 mm² (90% CI: -0.864 to -0.049), which was statistically significant by a 1-sided test. The clinical significance of this difference is unclear. There was a trend (p=0.07) for more subjects receiving low-intensity pulsed US to be judged as healed by participating physicians at the end of the 16-week study period.
(65% [33/51] of ultrasound versus 46% [23/50] sham subjects). While there was not a statistically significant improvement in the rate of healing, improvements in intermediate outcomes and corroborating evidence from trials of patients with similar indications, e.g., fracture nonunion, make it very likely that this treatment is efficacious for delayed union.

**Stress Fractures**

Rue et al. examined the effect of 20-minute daily low-intensity pulsed US on tibial stress fracture healing issues such as pain, function, and resumption of professional and personal activities in 26 military recruits.\(^\text{17}\) The delay from onset of symptoms to diagnosis was 32 days in the US group and 28 days in the placebo group. Pulsed US did not significantly reduce the healing time for the tibial stress fractures; the time to return to duty was 56 days in each group.

**Osteotomy Sites**

In 2013, Urita et al. published a small (n=27) quasi-randomized study (alternating assignment) of low-intensity pulsed US after ulnar -shortening osteotomy for ulnar impaction syndrome or radial -shortening osteotomy for Kienbock disease.\(^\text{18}\) Patients in the US group received once-daily 20-minute US treatments for at least 12 weeks postoperatively. Blinded evaluation of radiographic healing showed that US reduced the mean time to cortical union by 27% (57 vs. 76 days) and endosteal union by 18% (121 vs. 148 days). At the time of endosteal healing, the 2 groups had similar results on the Modified Mayo Wrist Score and no pain at the osteotomy site. Limitations of this study include lack of a sham control and the long interval between the 16 and 24 week assessments, which may have increased group differences. Additionally, clinical outcomes appear to have been assessed only at the time of radiographic healing and did not show any differences at this time point. Additional study is needed to determine with greater certainty the effect of low-intensity pulsed US on healing of osteotomy sites.

**Distraction Osteogenesis**

The 2009 systematic review by Busse et al. found 3 trials of distraction osteogenesis that used a variety of surrogate outcome measures with inconsistent results and provided very low-quality evidence of accelerated functional improvement.\(^\text{9}\) In 2011, a small (n=36) nonblinded RCT of
low-intensity pulsed US found no significant differences between active and control groups in efficacy measures, although the treatment period (fixator gestation period) was decreased by more than 1 month.\textsuperscript{19} A 2014 study randomized 21 patients undergoing callus distraction for posttraumatic tibial defects to pulsed US or no treatment (controls).\textsuperscript{20} In this nonblinded study, US shortened healing by 12 d/cm and the total fixator time by 95 days. Double-blind trials with a larger number of subjects are needed to evaluate the health benefits of this procedure.

Ongoing and Unpublished Clinical Trials

The Trial to Evaluate Ultrasound in the Treatment of Tibial Fractures (TRUST) (NCT00667849) was a trial of low-intensity US for tibial fractures. This was a double-blind trial with sham US control, and was scheduled to enroll 500 patients with open or closed tibial fracture amenable to intramedullary nail fixation. The primary outcome measure was radiographic healing at up to 1 year, and a secondary outcome was the rate of fracture nonunion. According to the posting on www.Clinicaltrials.gov, “The study was terminated due to futility,” indicating that futility analysis was performed and that further study would be unlikely to result in a significant effect of treatment.

An industry-sponsored randomized sham-controlled trial of low-intensity pulsed ultrasound for lumbar spine fusion (NCT00744861) was terminated after interim analysis. The primary outcome measure was radiographic fusion success at up to 1 year, and a secondary outcome was pain/disability. The study had a targeted enrollment of 310 patients with completion expected in 2012.

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.
**2008 Input**

In response to requests for input from physician specialty societies and academic medical centers for the 2008 policy update, input was received from 1 physician specialty society while this policy was under review. Physician input obtained through the American Academy of Orthopaedic Surgeons agreed with the positions regarding the criteria for medical necessity and the conditions that are considered investigational (e.g., delayed union and open/unstable grade II or III fractures).

**2011 Input**

In response to requests, input was received through 2 physician specialty societies and 1 academic medical center for the policy review in January 2011. Input supported the use of US 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 a different reviewer supported including fractures of the talus and sesamoids as additional risk factors.

**2012 Input**

In response to requests, input was received through four academic medical centers for the policy review in December 2012. Input supported the use of low-intensity US in delayed union and nonunion of bones excluding the skull and vertebra, and in fresh closed fractures at high risk for delayed fracture healing or nonunion. Input agreed that other applications of low-intensity US 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.
Summary of Evidence

There is evidence from published studies that ultrasound (US) improves healing rates in closed fresh fractures, delayed union, and fracture nonunion. As a result, US may be considered medically necessary for these indications. For treatment of open, fresh fractures, the evidence is less consistent across randomized controlled trials, and systematic reviews do not report strong conclusions on efficacy of US for improving healing when data on closed and open fresh fractures are combined. Most fresh closed fractures heal without complications with the use of standard fracture care, i.e., closed reduction and cast immobilization. Therefore, the most appropriate candidates for US treatment may be those with closed fractures at high risk for delayed fracture healing or nonunion. Based on the available evidence and support from clinical input, low-intensity US treatment may be considered medically necessary for fresh fractures (closed), delayed union of fractures, and nonunion of fractures.

Evidence is insufficient to evaluate health outcomes with use of low-intensity US as a treatment of congenital pseudarthroses, arthrodesis of the appendicular skeleton, or spinal fusions. Use of US for these conditions is considered investigational. Based on one small trial with results showing no benefit to use of US treatment in the treatment of stress fractures, this is considered investigational.

Practice Guidelines and Position Statements

The United Kingdom’s National Institute for Health and Clinical Excellence (NICE) updated their guidance on low-intensity pulsed US for the treatment of non-union and delayed fracture healing in 2013. NICE reached the following conclusions:

1.1. The case for adopting the EXOGEN ultrasound bone healing system to treat long-bone fractures with nonunion (failure to heal after 9 months) is supported by the clinical evidence, which shows high rates of fracture healing.
1.2. The EXOGEN ultrasound bone healing system to treat long-bone fractures with nonunion is associated with an estimated cost saving of £1164 per patient compared with current management, through avoiding surgery.
1.3. There is some radiological evidence of improved healing when the EXOGEN ultrasound bone healing system is used for long-bone fractures with delayed healing (no radiological evidence of healing after approximately 3 months). There are substantial uncertainties about the rate at which bone healing progresses without adjunctive treatment between 3 and 9 months after fracture, and about whether or not surgery
would be necessary. These uncertainties result in a range of cost consequences, some cost-saving and others that are more costly than current management.

The American Academy of Orthopaedic Surgeons (AAOS) published 2009 guidelines on the treatment of distal radius fractures. AAOS provided a weak recommendation for use of US for adjuvant treatment of distal radius fractures. This recommendation was based on results from 2 studies that used non-validated patient outcome measures.

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

The U.S. Preventive Services Task Force has not addressed ultrasound accelerated fracture healing devices.

**Medicare National Coverage**

Effective January 1, 2001, ultrasonic osteogenic stimulators are 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 non-invasive osteogenic devices. Ultrasonic osteogenic stimulators for fresh fractures and delayed unions remain non-covered.

**Regulatory Status**

The Sonic Accelerated Fracture Healing System, SAFHS® (also referred to as Exogen 2000®) was initially cleared for marketing by FDA in October 1994 as a 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. FDA product code: LPQ.


### History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>01/97</td>
<td>Add to Durable Medical Equipment Section - New Policy</td>
</tr>
<tr>
<td>08/17/99</td>
<td>Replace policy - Updated; new indications.</td>
</tr>
<tr>
<td>11/05/99</td>
<td>Replace policy - New CPT code; policy unchanged.</td>
</tr>
<tr>
<td>09/21/00</td>
<td>Replace policy - New indication for treatment of fracture nonunions.</td>
</tr>
<tr>
<td>01/18/01</td>
<td>Replace Policy - Corrections – Policy Guidelines, under fracture location, the name should say “Jones” fracture, not Jone’s; under Nonunions,“ fourth bullet should say the patient can be adequately “immobilized,” not “mobilized.”</td>
</tr>
<tr>
<td>04/15/03</td>
<td>Replace policy - Policy reviewed with 2002 updates and new references added. Policy Statement unchanged.</td>
</tr>
<tr>
<td>06/08/04</td>
<td>Replace policy - Policy updated with literature review; policy statement unchanged. No further literature reviewed scheduled.</td>
</tr>
<tr>
<td>06/14/05</td>
<td>Replace policy - Policy updated with literature search; policy statement revised to explicitly state that ultrasound treatment of open fracture is investigational. Information on Medicare policy added.</td>
</tr>
<tr>
<td>08/09/05</td>
<td>Replace policy - Policy updated with literature review for November 2004 through May 2005 and new Medicare coverage decision; policy statement unchanged.</td>
</tr>
<tr>
<td>05/26/06</td>
<td>Update Scope and Disclaimer - No other changes.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>09/12/06</td>
<td>Replace policy - Policy updated with literature search; no change in policy statement; policy changed from AR to BC. Policy guideline regarding &quot;non-weight bearing removed.</td>
</tr>
<tr>
<td>03/11/08</td>
<td>Replace policy - Policy updated with literature search; no change to the policy statement. Policy guidelines updated; references added.</td>
</tr>
<tr>
<td>11/10/09</td>
<td>Replace policy - Policy updated with literature search; rationale section extensively revised. Use in stress fractures added as investigational in the policy statement. References added.</td>
</tr>
<tr>
<td>03/08/11</td>
<td>Replace policy - Policy updated with literature search, clinical input reviewed, references reordered. Policy statements modified by moving information from policy guidelines to policy statements about risk factors for nonunion.</td>
</tr>
<tr>
<td>11/08/11</td>
<td>Replace policy – Policy updated with literature search through July 2011; references 12 and 13 added; treatment of delayed unions considered medically necessary. Within the Policy Guidelines, definitions for fresh fracture, nonunion and delayed union have been added or refined.</td>
</tr>
<tr>
<td>07/25/12</td>
<td>Update Related Policy – 7.01.529 Title changed to: Electrical Bone Growth Stimulation of the Appendicular Skeleton.</td>
</tr>
<tr>
<td>08/24/12</td>
<td>Update Coding Section – ICD-10 codes now have a 10/01/2014 effective date.</td>
</tr>
<tr>
<td>11/27/12</td>
<td>Replace policy. Policy revised with arthrodesis added to investigational statement. Policy guidelines revised with definition of delayed unions vs. nonunion. Rationale revised based on literature review through July 2012. References 1, 5, 15 added; other references renumbered or removed. Policy statement had new investigational condition added.</td>
</tr>
<tr>
<td>12/19/12</td>
<td>Update Related Policies; change policy title for 7.01.85.</td>
</tr>
<tr>
<td>02/13/13</td>
<td>Replace policy. Rationale section updated based on input from 4 academic medical centers and a literature review through July 2012. Practice guidelines updated with addition of American Academy of Orthopaedic Surgeons (AAOS) recommendation. Reference 17 added; others renumbered. Policy statement unchanged.</td>
</tr>
<tr>
<td>03/10/14</td>
<td>Replace policy. Added non-union of previous surgically-treated fractures to medical necessity policy statement and added fresh surgically-treated closed fractures to investigational policy statement. Added Jones Fracture to definition of terms. Policy updated with literature review through November 18, 2013, references 12, 16, and 18 added; others renumbered/removed. Policy statements changed as noted. ICD-9 and ICD-10 diagnosis codes removed; these are not utilized in adjudication of the policy.</td>
</tr>
<tr>
<td>04/24/15</td>
<td>Annual Review. Policy updated with literature review through November 25, 2014; references 11 and 20 added; reference 5 corrected; policy statements unchanged. Remove ICD-9 and ICD-10 codes removed; these are not utilized in policy</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>03/24/17</td>
<td>Policy moved into new format; no change to policy statements.</td>
</tr>
<tr>
<td>09/01/17</td>
<td>Note added that this policy has been revised. Added link to revised policy that will become effective December 21, 2017.</td>
</tr>
</tbody>
</table>

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2017 Premera All Rights Reserved.

**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.
Discrimination is Against the Law

Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:
- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-722-1471 (TTY: 800-842-5357).

Oromo (Cushite):

Français (French):

Kreyòl ayisyen (Creole):
Avi sila a gen Enfòmasyon Enpòtan Idayann. Avi sila a kapab genyen enfòmasyon enpòtan konsènan aplikasyon w lan oswa konse nâng kouvèti asirans lan atravè Premera Blue Cross. Kapab genyen dat ki enpòtan nan avi sila a. Ou ka gen pou pran kék aksyon avan sèten dat limit pou ka kente kouvèti asirans sante w la oswa pou yo ka ede w avèk depans yo. Se dwa w pou resevwa enfòmasyon sa a ak asistans nan lang ou pale a, san ou pa gen pou peye pou sa. Rate nan 800-722-1471 (TTY: 800-842-5357).

Deutsche (German):

Hmoob (Hmong):
Tsaab nthaw tshaj xo no muaj cov ntsibab lus tseem ceeb. Tëj zaum tsab nthaw tshaj xo no muaj cov ntsibab lus tseem ceeb xog koj daim nthaw thov kev pab los yoy koj qhov kev pab cuam los nthaw Premera Blue Cross. Tëj zaum muaj cov hnb tseem ceeb uas tuu rau hauv daim nthaw no. Tëj zaum koj kuj yuav tau uu qee yam uu pab koj uu tis puub dhaa cov cajy nyoy uas teev tseg rau hauv daim nthaw no mas koj thaj yuav tau lua beeks kev pab cuam kho muaj los yoy koj qhov kev pab thëm tæj një kho mbo nthaw. Koj muaj cai kom laww muab cov ntsibab lus uu no uas tuu muab saa uu koj hom lus pub dawb rau koj. Hu rau 800-722-1471 (TTY: 800-842-5357).

Ilokano (Ilocano):
Daytoy a Pakdaar kat naglao iti Napateg nga Impormasion. Daytoy a pakdaar mabalin nga adda kat naglao iti napateg nga impormasion maianggep iti aplikasyonee waya coverag babaen iti Premera Blue Cross. Daytoy ket mabalin dagiti importante a pelsa iti daytoy a pakdaar. Mabalin nga adda rumbeng nga aramidenyo nga addang sakbay dagiti partikular a naituding nga adda taway tapo mapagataglawdyoy ti coverag ti salay-ayno waya tulong kadagit gastos. Adda karbenganyo a mangala iti daytoy nga impormasion ken tulong iti bukodyo a pagasasao nga awan ti bayadanyo. Tumawag ti numero nga 800-722-1471 (TTY: 800-842-5357).

Italiano (Italian):

中文 (Chinese):
本通知有重要的訊息。本通知可能會有關於您透過 Premera Blue Cross 提交的申請或保單的重要訊息。本通知可能會有重要的日期。您可能需要在截止日期之前採取行動，以保留您的健康保險或費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話 800-722-1471 (TTY: 800-842-5357).

037338 (07-2016)
Japanese (Japanese):  
この通知には重要な情報が含まれています。この通知には、Premera Blue Crossの申請または補償範囲に関する重要な情報が含まれている場合があります。この通知に記載されている可能性がある重要な日付をご確認ください。健康保険を含むサポートを維持するには、特定の期限までに行動を取りなけれはならない場合があります。ご希望のご言語による情報とサポートが無料で提供されます。800-722-1471（TTY: 800-842-5357）までお電話ください。

한국어 (Korean):  
본 통지서에는 중요한 정보가 들어 있습니다. 즉 이 통지서는 귀하의 신청에 관하여 그리고 Premera Blue Cross를 통해 커버리지에 관한 정보를 포함하고 있습니다. 본 통지서에는 빠짐이 되는 날짜들이 있을 수 있습니다. 귀하의 귀하 전 간 커버리지를 계적 유지하거나 비용을 절감하기 위해서 일정한 마감까지 조치를 취해야 할 필요가 있을 수 있습니다. 귀하는 이러한 정보와 도움을 귀하의 언어로 사용할 수 있는 권리가 있습니다. 800-722-1471（TTY: 800-842-5357）로 전화하십시오。

Polski (Polish):  
To ogłoszenie może zawierać ważne informacje. To ogłoszenie może zawierać ważne informacje odnośnie Państwa wniosku lub zakresu świadczeń poprzez Premera Blue Cross. Prosimy zwrócić uwagę na kluczowe daty, które mogą być zawarte w tym ogłoszeniu aby nie przekroczyć terminów w przypadku utrzymania polisy ubezpieczeniowej lub pomocy związanej z kosztami. Macie Państwo prawo do bezpłatnej informacji we własnym języku. Zadzwoncie pod 800-722-1471（TTY: 800-842-5357）.

Português (Portuguese):  
Este aviso contém informações importantes. Este aviso poderá conter informações importantes a respeito de sua aplicação ou cobertura por meio do Premera Blue Cross. Poderão existir datas importantes neste aviso. Talvez seja necessário que você tome providências dentro de determinados prazos para manter sua cobertura de saúde e ajuda de custos. Você tem o direito de obter esta informação e ajuda em seu idioma e sem custos. Ligue para 800-722-1471（TTY: 800-842-5357）.

Română (Romanian):  

Russian (Russian):  
Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть указаны ключевые даты. Вам, возможно, потребуется привести меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471（TTY: 800-842-5357）.

Spanish (Spanish):  
Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. Es posible que haya fechas claras en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471（TTY: 800-842-5357）.

.Tagalog (Tagalog):  
Ang Paunawa na ito ay naglalaman ng mahalagang impormasyon. Ang paunawa na ito ay naglalaman ng mahalagang impormasyon tungkol sa iyong aplikasyon o pagkakasamang paglalatay sa iyong Premera Blue Cross. Samahan ang mga halaga at pananaluhang panahon unang mapanatili ang iyong aplikasyon sa kahalagahan ng tulong sa walaang gastos. Magkaratap na ka makakuha ng ganitong impormasyon at tulong sa iyong wika ng walaang gastos. Turnaw sa 800-722-1471（TTY: 800-842-5357）.

ไทย (Thai):  
ประกาศนี้มีข้อมูลสําคัญที่เกี่ยวกับการดำเนินการของคุณที่เกี่ยวกับสัญญาประกัน Premera Blue Cross และคุณมีสิทธิที่จะได้รับข้อมูลและความช่วยเหลือในการเติมเต็มสัญญาประกันที่เกี่ยวข้อง ถ้าคุณมีความประสงค์ที่จะเรียนรู้ข้อมูลที่เกี่ยวกับการเตรียมความพร้อมในการจ่ายค่านายหน้า โปรดติดต่อ 800-722-1471 (TTY: 800-842-5357).

Українська (Ukrainian):  
Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо страхувального покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути вказані у цьому повідомленні. Існує імовірність того, що Вам треба буде здійснити певні кроки у конкретні кінцеві строки для того, щоб зберегти Ваше медичне страхування або отримати фінансову допому. У Вас є право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дозвінть за номером телефону 800-722-1471（TTY: 800-842-5357）.

Tiếng Việt (Vietnamese):  
Thông báo này cung cấp thông tin quan trọng. Thông báo này có thông tin quan trọng về đơn xin tham gia hoặc hỗ trợ bảo hiểm của quý vị qua quáng triều Premera Blue Cross. Xin xem ngày quan trọng thông báo này. Quý vị có thể phải thực hiện những thông báo đúng trong thời hạn đề, để duy trì bảo hiểm sức khỏe hoặc được trợ giúp thêm về chi phí. Quý vị có quyền được biết thông tin này và được trợ giúp bằng ngôn ngữ của mình miễn phí. Xin gọi số 800-722-1471（TTY: 800-842-5357）.