Medical Policy

BlueCross BlueShield of Kansas
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Title: Ultrasound Accelerated Fracture Healing Device

Professional
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Populations	Interventions	Comparators	Outcomes
Individuals: • With fresh closed fractures	Interventions of interest are: • Low-intensity pulsed ultrasound	Comparators of interest are: • Conservative care	Relevant outcomes include: • Symptoms • Morbid events • Functional outcomes • Quality of life
Individuals: • With open fractures or surgically treated closed fractures	Interventions of interest are: • Low-intensity pulsed ultrasound	Comparators of interest are: • Conservative care	Relevant outcomes include: • Symptoms • Morbid events • Functional outcomes • Quality of life
Individuals: • With fracture nonunion	Interventions of interest are: • Low-intensity pulsed ultrasound	Comparators of interest are: • Conservative care • Surgery	Relevant outcomes include: • Symptoms • Morbid events • Functional outcomes • Quality of life

Populations	Interventions	Comparators	Outcomes
Individuals: • With delayed fracture union	Interventions of interest are: • Low-intensity pulsed ultrasound	Comparators of interest are: • Conservative care • Surgery	Relevant outcomes include: • Symptoms • Morbid events • Functional outcomes • Quality of life
Individuals: • With stress fractures	Interventions of interest are: • Low-intensity pulsed ultrasound	Comparators of interest are: • Conservative care	Relevant outcomes include: • Symptoms • Morbid events • Functional outcomes • Quality of life
Individuals: • With osteotomy sites	Interventions of interest are: • Low-intensity pulsed ultrasound	Comparators of interest are: • Conservative care	Relevant outcomes include: • Symptoms • Morbid events • Functional outcomes • Quality of life
Individuals: • With distraction osteogenesis	Interventions of interest are: • Low-intensity pulsed ultrasound	Comparators of interest are: • Conservative care	Relevant outcomes include: • Symptoms • Morbid events • Functional outcomes • Quality of life

DESCRIPTION

Low-intensity pulsed ultrasound has been investigated as a technique to accelerate healing of fresh fractures, delayed unions, and nonunions. Ultrasound 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. Ultrasound 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 definition of a fracture nonunion has remained controversial. For electrical bone growth stimulators, the U.S. Food and Drug Administration (FDA) 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, ie, 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 x-rays fail to show any further healing. According to the FDA labeling for a low-intensity pulsed ultrasound 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 1 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.

Regulatory Status

The Sonic Accelerated Fracture Healing System (SAFHS® currently called Exogen 2000®; Bioventus) 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.

POLICY

A. Low-intensity pulsed ultrasound treatment may be considered **medically necessary** when used as an adjunct to conventional management (ie, closed reduction and cast immobilization) for the treatment of fresh, closed fractures in skeletally mature individuals. Candidates for ultrasound treatment are those at high risk for delayed fracture healing or nonunion. These risk factors may include either locations of fractures or patient comorbidities and include the following:

   1. Patient comorbidities:
      a) Diabetes
      b) Steroid therapy
      c) Osteoporosis
      d) History of alcoholism
      e) History of smoking

   2. Fracture locations:
      a) Jones fracture
      b) Fracture of navicular bone in the wrist (also called the scaphoid)
      c) Fracture of metatarsal
      d) Fractures associated with extensive soft tissue or vascular damage
      e) Tibial diaphysis fracture that is closed or grade I open (skin opening is ≤1 cm with minimal muscle contusion)

B. Low-intensity pulsed ultrasound treatment may be considered **medically necessary** as a treatment of delayed union of bones, including delayed union of previously surgically-treated fractures, and excluding the skull and vertebra. (See Policy Guidelines for definition of delayed union.)

C. Low-intensity pulsed ultrasound treatment may be considered **medically necessary** as a treatment of fracture nonunions of bones, including nonunion of previously surgically-treated fractures, and excluding the skull and vertebra. (See Policy Guidelines for definition of nonunion.)

D. Other applications of low-intensity pulsed ultrasound treatment are **experimental / investigational**, including, but not limited to, treatment of congenital pseudarthroses, open fractures, fresh surgically-treated closed fractures, stress fractures, and arthrodesis or failed arthrodesis.

Policy Guidelines

1. Fresh (Acute) Fracture
   A. There is no standard definition for a "fresh" fracture. A fracture is most commonly defined as fresh for 7 days after the fracture occurs,[6,7,11] but there is variability. For example, 1 study defined fresh as less than 5 days after fracture,[9] while another defined fresh as up to 10 days after fracture.[8] Most

fresh closed fractures heal without complications with the use of standard fracture care, ie, closed reduction and cast immobilization.

2. Delayed Union
   A. 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.
3. Nonunion
   A. 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).[1]
   B. The definition of nonunion in 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 nonunions:
      1) At least 3 months have passed since the date of the fracture, AND
      2) serial radiographs have confirmed that no progressive signs of healing have occurred, AND
      3) the patient can be adequately immobilized and is of an age when he/she is likely to comply with non-weight bearing.

RATIONALE

The most recent MEDLINE literature update was conducted through July 1, 2016.

Fresh Fractures

Systematic Reviews With Mixed Populations of Fresh Closed Fractures, Open Fractures, and Surgically Treated Closed Fractures

A 2002 meta-analysis conducted by Busse et al supported the use of low-intensity pulsed ultrasound (LIPUS) as a technique for fractures treated nonoperatively.[2] This review was updated in 2009 and included RCTs of LIPUS for any type of fracture.[3] Thirteen trials were included; in 5 of them, patients were managed conservatively; in 8 studies, patients received ultrasound (US) therapy after operative management (distraction osteogenesis in 3 studies, bone graft for nonunion in 1, 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.

The trials of surgically managed fresh (open) fractures outcomes were inconsistent; 4 trials provided low-quality evidence for acceleration of healing by US therapy. Pooled results of 2 trials showed a nonsignificant 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.[4] Selected studies were limited in methodologic quality, with all having some evidence of bias. There was very limited evidence on functional outcomes. Pooling results from 8 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 surgically treated fractures raised the possibility that LIPUS may be effective in reducing healing time in conservatively managed fractures, but a test for subgroup differences did not confirm that difference between the subgroups. The reviewers concluded that while a potential benefit of US for acute fractures could not be ruled out, currently available evidence was insufficient to support its routine use.

Fresh Closed Fractures

This evidence review on fresh fractures is based in part on a 1995 TEC Assessment, which concluded that US fracture healing met TEC criteria for the indications labeled by the U.S. Food and Drug Administration (FDA): treatment of fresh closed fractures of the tibia or distal radius (ie, Colles fractures).[5] Since that TEC Assessment, numerous randomized controlled trials (RCTs) and systematic reviews of clinical trials have evaluated use of US to improve healing in fresh fractures.

In a 1997 multicenter RCT by Kristiansen et al, 60 patients with dorsally angulated fractures of the distal radius treated with manipulation and casting were randomly assigned to 10 weeks of daily treatment with a pulsed US device or an inactive device.[6] All patients started US within 7 days of 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.[7] Treatment began within 7 days postfracture and consisted of one 20-minute daily session. Time-to-healing was 86 days in the treatment group and 114 days in the control group ($p=0.01$); time to overall (clinical and radiographic) healing was 96 days in the treatment group compared with 154 days in the control group ($p<0.001$).

Scaphoid fractures were treated with US in a 2000 study conducted in Germany.[8] Fifteen patients with fresh scaphoid fractures (≤10 days) were randomly assigned to treatment and 15 to a placebo device. Healing was assessed by computed tomography (CT) scans every 2 weeks. Fractures treated with US healed faster (43.2 days) than with placebo (62 days; $p<0.01$). 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%).

The benefit of LIPUS may depend on the location and type of bone. Lubbert et al performed a multicenter, double-blind RCT of US treatment of fresh (<5 days) clavicle shaft fractures.[9] Patients were taught to use US devices for 20 minutes daily 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 expressed as hours of activity (work, household work, sport), and analgesic use. A total of 120 patients (61 active, 59 placebo) started treatment.

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 terms of analgesic use and mean VAS scores were not significant. The time to healing with these fractures is substantially lower than in other studies.

Analysis of an FDA-required postmarketing registry was published by Zura et al in 2015.[10] This study included 4190 patients, representing 73% of patients in the registry with fresh fractures. The healing rate was 96% for patients who were compliant; 11% of patients were noncompliant or withdrew from the study. Factors found to reduce healing rate were open fracture, current smoking, diabetes, vascular insufficiency, osteoporosis, cancer, rheumatoid arthritis, and prescription nonsteroidal anti-inflammatory drugs. Older age (≥60 years) did not reduce the healing rate.

Section Summary: Fresh Closed Fractures
A 1995 TEC Assessment concluded that ultrasound (US) fracture healing met TEC criteria for the indications labeled by the U.S. Food and Drug Administration (FDA): treatment of fresh closed fractures of the tibia or distal radius (ie, Colles fractures).[5] Since that TEC Assessment, a number of RCTs and systematic reviews have evaluated LIPUS to improve healing in fresh fractures. A 2009 systematic review found that LIPUS significantly accelerated radiographic healing of fractures in all 3 RCTs of conservatively managed fresh fractures that assessed this outcome. More recently, in a 2014 Cochrane review that included 12 trials but did not distinguish between closed and open fractures; subgroup analysis found that pulsed US may be effective in reducing healing time in conservatively managed fractures. The efficacy of LIPUS to accelerate fracture healing may depend on the location and type of bone along with risk factors for healing.

Open Fractures and Surgically Treated Closed Fractures
For the treatment of open fractures, data are conflicting on the efficacy of LIPUS, 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 fixed with an intramedullary rod to undergo additional treatment with an active or inactive US device.[11] US treatment began within 3 days of surgery, and with 1 exception, within 7 days of injury. Time-to-healing did not differ significantly between groups, leading the authors to conclude that there was no benefit in surgically 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 LIPUS.[12] US treatment began 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 shorter in those in the US group.

In 2011, Dijkman et al reported a substudy of 51 patients from a larger RCT that enrolled patients with open or closed tibial shaft fractures treated surgically with an intramedullary nail.[13] A 2014 publication from Busse et al reported a sham-controlled pilot of the industry-sponsored TRUST trial to determine feasibility for the larger trial.[14] According to www.ClinicalTrials.gov (NCT00667849), last updated November 2015, 501 patients were enrolled, but the trial was "terminated due to futility" at study midpoint. Results posted on the website show no benefit for the primary outcome measures of 36-Item Short-Form Health Survey Physical Component Summary score or days to radiographically confirmed healing.

Section Summary: Open Fractures and Surgically Treated Closed Fractures
Findings are not consistent for studies of fresh open fractures. The inconsistent results from the 2 small randomized trials and the negative findings of the meta-analysis do not support use of LIPUS for treating open fractures. In addition, a large and well-designed sham-controlled trial of LIPUS for surgically treated fresh tibial fractures was terminated due to futility after half of the patients completed the study.

Fracture Nonunion

The evidence on nonunion of fractures is based on data presented to FDA as part of the approval process for the Sonic Accelerated Fracture Healing System (SAFHS). The following data were reported and are included in the device package insert.[15]

- 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 healed with use of low-intensity US. Time-to-healing was 173 days. The healing 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.

In 2015, Zura et al analyzed data from a FDA-required postmarketing registry that included 767 patients with chronic fracture nonunion.[16] Patients with chronic (>1 year) nonunion were selected if they had the following information recorded: date of fracture, start of US treatment, end of US treatment, and healed/failed status using both clinical and radiographic outcomes. Patients had undergone an average of 3.1 prior surgical procedures without success. The reported healing rate was compared with the expected healing rate for chronic nonunion, which is negligible without intervention. With an average of 179.5 days of US treatment, the overall healing rate was 86.2%. For patients with a nonunion of at least 5 years in duration (n=98), the healing rate was 82.7%; for patients with a nonunion of greater than 10 years (n=12), the healing rate was 63.2%. Age was the only factor affecting healing rate.

A 2007 study used prospectively defined criteria to analyze 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).[17] Included in the analysis were 71 patients at least 3 months from the last surgical intervention who did not show any healing improvements in the 3 months before US treatment (average fracture age, 257 days; range, 180-781 days). All patients completed follow-up (average, 2.7 years) by questionnaire, or by phone, if needed. The overall healing rate was 73%, at an average 184 days to healing (range, 52-739 days). No differences in healing rates for open and closed fractures were observed.

Section Summary: Fracture Nonunion
The evidence on US for nonunion includes prospective cohort studies and a large registry study. Due to the low likelihood of healing without intervention, cohort studies demonstrating high rates of healing are considered adequate evidence to demonstrate improved outcomes for this

indication. The largest study analyzed data from a registry and focused on patients with chronic nonunion. Many of these patients had failed to heal despite surgical treatment, but had a high rate of healing with US.

Delayed Fracture Union

In 2010, Schofer et al reported an industry-sponsored, multicenter, randomized, double-blinded, sham-controlled trial of LIPUS in 101 patients with delayed union of the tibia.[18] 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 end point. The primary analysis was intention-to-treat with imputation of missing values. Mean improvement in BMD was 34% (90% CI, 14% to 57%) greater for US-treated subjects than for sham-treated subjects. Analysis of "completers" showed a medium effect size (0.53) of the treatment. A mean reduction in bone gap area (as measured on a log scale) also favored US treatment, with a mean change in log gap area of -0.131 mm^2 for active treatment and -0.097 mm^2 for sham (effect size, -0.47; 95% CI, -0.91 to -0.03). Untransformed data showed a difference between groups of -0.457 mm^2 (90% CI, -0.864 to -0.049), which was statistically significant. The clinical significance of this difference is unclear. There was a trend (p=0.07) for more subjects receiving LIPUS to be judged as healed by participating physicians at the end of the 16-week study period (65% [33/51] of US vs 46% [23/50] of sham).

Section Summary: Delayed Fracture Union

The best evidence for US treatment for delayed fracture union is from a moderately sized (N=101), double-blinded, sham-controlled trial. Analysis of patients who completed the study showed a moderate effect size for increased bone mineral density and a trend for increased rate of clinical healing. 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 (eg, fracture nonunion) make it very likely that this treatment is efficacious for delayed union.

Stress Fractures

Rue et al reported a double-blind RCT that examined the effects of LIPUSS 20 minutes daily on tibial stress fracture healing issues such as pain, function, and resumption of professional and personal activities in 26 military recruits.[19] The delay from onset of symptoms to diagnosis was 32 days in the US group and 28 days in the placebo group. This study found no significant difference in healing time with pulsed US treatment, with a mean time of return to duty of 56 days for both active and sham US groups.

Section Summary: Stress Fractures

One small RCT was identified on LIPUS for the treatment of tibial stress fractures. LIPUS did not significantly reduce the healing time for the tibial stress fractures in this double-blind study. Additional study in a larger sample of patients is needed to determine the effect of US treatment on stress fractures with greater certainty.

Osteotomy Sites

In 2013, Urita et al published a small (N=27) quasi-randomized study (alternating assignment) of LIPUS after ulnar-shortening osteotomy for ulnar impaction syndrome or radial-shortening osteotomy for Kienbock disease.[20] Patients in the US group received a daily 20-minute US treatment for at least 12 weeks postoperatively. Blinded evaluation of radiographic healing showed that US reduced the mean time to cortical union by 27% (57 days vs 76 days) and endosteal union by 18% (121 days vs 148 days). At the time of endosteal healing, the 2 groups had similar results as measured using the Modified Mayo Wrist Score and no pain at the osteotomy site.

Section Summary: Osteotomy Sites

One small quasi-randomized study was identified on use of US for osteotomy sites. This study lacked a sham control and has a 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 the effect of LIPUS 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.[3] In 2011, a small (N=36) nonblinded RCT of LIPUS 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.[21] A 2014 study randomized 21 patients undergoing callus distraction for posttraumatic tibial defects to LIPUS or no treatment (controls).[22] In this nonblinded study, US shortened healing by 12 d/cm and the total fixator time by 95 days.

Section Summary: Distraction Osteogenesis

The literature on LIPUS for distraction osteogenesis consists of small trials with inconsistent results. Double-blind trials with larger numbers of subjects are needed to evaluate the health benefits of this procedure.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Unpublished			
NCT00667849[a]	Trial to Evaluate UltraSound in the Treatment of Tibial Fractures (TRUST)	501	Terminated (futility)
NCT00744861[a]	EXO-SPINE: A Prospective, Multi-center, Double-blind, Randomized, Placebo Controlled Pivotal Study of Ultrasound as Adjunctive Therapy for Increasing Posterolateral Fusion Success Following Single Level Posterior Instrumented Lumbar Surgery	310	Terminated (interim analysis)

NCT: national clinical trial.

[a] Denotes industry-sponsored or cosponsored trial.

Summary of Evidence

For individuals who have fresh closed fractures who receive low-intensity pulsed ultrasound (LIPUS), the evidence includes randomized controlled trials (RCTs) and systematic reviews of RCTs. Relevant outcomes are symptoms, morbid events, functional outcomes, and quality of life. This evidence indicates that LIPUS improves clinical and radiographic healing for fresh closed fractures, although the magnitude of benefit may differ depending on the location of the bone and risk factors for healing. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who have open fractures or surgically treated closed fractures who receive LIPUS, the evidence includes RCTs. Relevant outcomes are symptoms, morbid events, functional outcomes, and quality of life. Results from RCTs of LIPUS for this patient population are mixed, and do not consistently demonstrate improved outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have fracture nonunion who receive LIPUS, the evidence includes prospective case series. Relevant outcomes are symptoms, morbid events, functional outcomes, and quality of life. The case series are considered adequate evidence for nonunions, due to the negligible chance of healing without intervention and the lack of other noninvasive alternatives. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who have delayed fracture union who receive LIPUS, the evidence includes an RCT. Relevant outcomes are symptoms, morbid events, functional outcomes, and quality of life. Evidence for ultrasound (US) treatment for delayed fracture union (a moderately sized double-blinded sham-controlled trial) showed a moderate effect size for increased bone mineral density and a trend toward increased rate of clinical healing with US treatment. In addition, improvements in intermediate outcomes (eg, radiographic appearance), combined with the efficacy of US for fresh closed fractures and fracture nonunion, make it very likely that this treatment is also efficacious for delayed union. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who have tibial stress fractures, osteotomy sites, or distraction osteogenesis who receive LIPUS, the evidence includes small RCTs and nonrandomized comparative trials. Relevant outcomes are symptoms, morbid events, functional outcomes, and quality of life. One small RCT was identified on US for the treatment of tibial stress fractures. LIPUS did not significantly reduce healing time for these fractures in this double-blind study. One small quasi-randomized study was identified on use of US for osteotomy sites. Clinical outcomes appear to have been assessed only at the time of radiographic healing and did not show any differences between groups at that time point. The literature on pulsed US for distraction osteogenesis (small trials) has shown inconsistent results. The evidence is insufficient to determine the effects of the technology on health outcomes.

Clinical Input Received Through 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 (eg, 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 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 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 4 academic medical centers for the policy review in December 2012. Input supported the use of low-intensity ultrasound 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 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.

Practice Guidelines and Position Statements

National Institute for Health and Clinical Excellence
The U.K.'s National Institute for Health and Clinical Excellence (NICE) published guidance in 2010 on LIPUS to promote fracture healing.[23] NICE concluded that this procedure can reduce fracture healing and is particularly beneficial for delayed healing and fracture nonunion.

NICE published a medical technology guidance on Exogen for the treatment of nonunion and delayed fracture healing in 2013.[24] 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 of bone healing without treatment between 3 and 9 months after fracture and need for surgery, cost consequences were uncertain.

American Academy of Orthopaedic Surgeons
The American Academy of Orthopaedic Surgeons (AAOS) published 2009 guidelines on the treatment of distal radius fractures.[25] AAOS provided a weak recommendation for use of

ultrasound for adjuvant treatment of distal radius fractures. This recommendation was based results from 2 studies that used nonvalidated patient outcome measures.

U.S. Preventive Services Task Force Recommendations
Not applicable.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT/HCPCS

20979	Low intensity ultrasound stimulation to aid bone healing, noninvasive (nonoperative)
E0760	Osteogenesis stimulator, low intensity ultrasound, noninvasive

ICD-9 Diagnoses

733.82	Malunion and nonunion of fracture nonunion of fracture
810.01	Fracture of clavicle, closed sternal end of clavicle
810.02	Fracture of clavicle, closed shaft of clavicle
810.03	Fracture of clavicle, closed acromial end of clavicle
811.01	Fracture of scapula, closed acromial process
811.02	Fracture of scapula, closed coracoid process
811.03	Fracture of scapula, closed glenoid cavity & neck of scapula
811.09	Fracture of scapula, closed other
812.01	Fracture of humerus, upper end, closed surgical neck
812.02	Fracture of humerus, upper end, closed anatomical neck
812.03	Fracture of humerus, upper end, closed greater tuberosity
812.09	Fracture of humerus, upper end, closed other
812.21	Shaft or unspecified part, closed shaft of humerus
812.41	Frac. Of humerus, lower end, closed supracondylar fracture of humerus
812.42	Fracture of humerus, lower end, closed lateral condyle
812.43	Fracture of humerus, lower end, closed medial condyle
812.49	Fracture of humerus, lower end, closed other
813.01	Frac. Of radius & ulna, upper end, closed olecranon process of ulna
813.02	Fracture of radius & ulna, upper end, closed coronoid process of ulna
813.03	Fracture of radius & ulna, upper end, closed monteggia's fracture
813.04	Fracture of radius & ulna, upper end, closed other & unsp. Proximal end radius
813.05	Fracture of radius & ulna, upper end, closed head of radius
813.06	Fracture of radius & ulna, upper end, closed neck of radius
813.07	Frac. Of radius/ulna, upper end, closed other & unsp. Proximal end of radius
813.08	Fracture of radius & ulna, upper end, closed radius with ulna, (any part)
813.21	Fracture of radius & ulna, shaft closed radius (alone)
813.22	Fracture of radius & ulna, shaft closed ulna (alone)
813.23	Fracture of radius & ulna, shaft closed radius with ulna
813.41	Fracture of radius & ulna, lower end closed colles' fracture

813.42 Fracture of radius & ulna, lower end closed distal end of radius (alone)
813.43 Fracture of radius & ulna, lower end closed distal end of ulna (alone)
813.44 Fracture of radius & ulna, lower end closed radius with ulna, lower end
813.45 Torus fracture of radius (alone)
813.46 Torus fracture of ulna (alone)
813.47 Torus fracture of radius and ulna
813.81 Fracture of radius & ulna, unspecified part closed radius (alone)
813.82 Fracture of radius & ulna, unspecified part closed ulna (alone)
813.83 Fracture of radius & ulna, unspecified part closed radius with ulna
814.01 Fracture of carpal bone(s), closed navicular (scaphoid) of wrist
814.02 Fracture of carpal bone(s), closed lunate (semilunar) bone of wrist
814.03 Fracture of carpal bone(s), closed triquetral (cuneiform) bone of wrist
814.04 Fracture of carpal bone(s), closed pisiform
814.05 Fracture of carpal bone(s), closed trapezium bone (larger multangular)
814.06 Fracture of carpal bone(s), closed trapezoid bone (smaller multangular)
814.07 Fracture of carpal bone(s), closed capitate bone (os magnum)
814.08 Fracture of carpal bone(s), closed hamate (unciform) bone
814.09 Fracture of carpal bone(s), closed other
815.01 Fracture of metacarpal bone(s), closed base of thumb (first) metacarpal
815.02 Fracture of metacarpal bone(s), closed base of other metacarpal bone(s)
815.03 Fracture of metacarpal bone(s), closed shaft of metacarpal bone(s)
815.04 Fracture of metacarpal bone(s), closed neck of metacarpal bones(s)
815.09 Fracture of metacarpal bone(s), closed multiple sites of metacarpus
816.01 Fracture of one or more phalanges of hand, closed middle or proximal
816.02 Fracture of one or more phalanges of hand, closed distal phalanx or phalanges
816.03 Fracture of one or more phalanges of hand, closed multiple sites
817.0 Multiple fractures of hand bones closed
818.0 Ill-defined fractures of upper limb closed
819.0 Multiple frac. Involving both upper limbs & upper limb with ribs/sternum, closed
820.20 Pertrochanteric fracture, closed trochanteric section, unspecified
820.21 Pertrochanteric fracture, closed intertrochanteric section
820.22 Pertrochanteric fracture, closed subtrochanteric section
820.8 Fracture of neck of femur unspecified part of neck of femur, closed
821.01 Shaft or unspecified part, closed shaft
821.21 Frac. Other & unspec. Parts, femur, lower end, closed condyle, femoral
821.22 Lower end, closed epiphysis, lower (separation)
821.23 Lower end, closed supracondylar fracture of femur
821.29 Frac. Other & unspec. Parts of femur, lower end, closed other
822.0 Fracture of patella closed
823.00 Fracture of tibia & fibula, upper end closed tibia alone
823.01 Fracture of tibia & fibula, upper end closed fibula alone
823.02 Fracture of tibia & fibula, upper end closed fibula with tibia
823.20 Fracture of tibia & fibula, shaft closed tibia alone
823.21 Fracture of tibia & fibula, shaft closed fibula alone
823.22 Fracture of tibia & fibula, shaft closed fibula with tibia
823.40 Torus fracture, tibia alone
823.41 Torus fracture, fibula alone
823.42 Torus fracture, fibula with tibia

823.80	Fracture of tibia & fibula, unspecified part closed tibia alone
823.81	Fracture of tibia & fibula, unspecified part closed fibula alone
823.82	Fracture of tibia & fibula, unspecified part closed fibula with tibia
824.0	Fracture of ankle medial malleolus, closed
824.2	Fracture of ankle lateral malleolus, closed
824.4	Fracture of ankle bimalleolar, closed
824.6	Fracture of ankle trimalleolar, closed
824.8	Fracture of ankle unspecified, closed
825.0	Fracture of one or more tarsal & metatarsal bones fracture of calcaneus, closed
825.20	Frac. Of other tarsal & metatarsal bones, closed unsp. Bone(s), foot (not toes)
825.21	Fracture of other tarsal & metatarsal bones, closed astragalus
825.22	Fracture of other tarsal & metatarsal bones, closed navicular (scaphoid), foot
825.23	Fracture of other tarsal & metatarsal bones, closed cuboid
825.24	Fracture of other tarsal & metatarsal bones, closed cuneiform, foot
825.25	Fracture of other tarsal & metatarsal bones, closed metatarsal bone(s)
825.29	Fracture of other tarsal & metatarsal bones, closed other
826.0	Fracture of one or more phalanges of foot closed
827.0	Other, multiple, & ill-defined fractures of lower limb closed
828.0	Multiple fractures, both lower limbs, lower/upper, & lower/ribs/sternum closed
905.1	Late eff. Of musc. & connective tissue frac. Of spine & trunk w/o spinal cord
905.2	Late eff. Of musc. & connective tissue fracture of upper extremities
905.3	Late eff. Of musc. & connective tissue fracture of neck femur
905.4	Late eff. Of musc. & connective tissue fracture of lower extremities
905.5	Late eff. Of musc. & connective tissue frac. Of multiple & unspecified bones
V54.10	Aftercare for healing traumatic fracture of arm, unspecified
V54.11	Aftercare for healing traumatic fracture of upper arm
V54.12	Aftercare for healing traumatic fracture of lower arm
V54.13	Aftercare for healing traumatic fracture of hip
V54.14	Aftercare for healing traumatic fracture of leg, unspecified
V54.15	Aftercare for healing traumatic fracture of upper leg
V54.16	Aftercare for healing traumatic fracture of lower leg
V54.19	Aftercare for healing traumatic fracture of other bone

ICD-10 Diagnoses *(Effective October 1, 2015)*

S42.011A	S42.015K	S42.022A	S42.031K	S42.111A	S42.115K
S42.011G	S42.015S	S42.022G	S42.031S	S42.111G	S42.115S
S42.011K	S42.017A	S42.022K	S42.032A	S42.111K	S42.121A
S42.011S	S42.017G	S42.022S	S42.032G	S42.111S	S42.121G
S42.012A	S42.017K	S42.024A	S42.032K	S42.112A	S42.121K
S42.012G	S42.017S	S42.024G	S42.032S	S42.112G	S42.121S
S42.012K	S42.018A	S42.024K	S42.034A	S42.112K	S42.122A
S42.012S	S42.018G	S42.024S	S42.034G	S42.112S	S42.122G
S42.014A	S42.018K	S42.025A	S42.034K	S42.114A	S42.122K
S42.014G	S42.018S	S42.025G	S42.034S	S42.114G	S42.122S
S42.014K	S42.021A	S42.025K	S42.035A	S42.114K	S42.124A
S42.014S	S42.021G	S42.025S	S42.035G	S42.114S	S42.124G
S42.015A	S42.021K	S42.031A	S42.035K	S42.115A	S42.124K
S42.015G	S42.021S	S42.031G	S42.035S	S42.115G	S42.124S

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REVISIONS

11-12-2014	Policy added to the bcbsks.com web site on 11-12-2014. Update effective for Professional on 11-12-2014. Effective for Institutional on 12-11-2014.
02-16-2015	In Coding section: ▪ Added ICD-10 diagnosis codes, effective October 1, 2015.
04-28-2015	Updated Description section.
	In Policy section: ▪ In Policy Guidelines, Item 1 A, added "There is no standard definition for a "fresh" fracture." and ",(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)"
	Updated Rationale section.
	Updated References section.
10-12-2016	Updated Description section.
	In Policy section: ▪ In Item A, added "pulsed" to read "Low-intensity pulsed ultrasound treatment may be considered medically necessary when used as an adjunct to conventional management (ie, closed reduction and cast immobilization) for the treatment of resh, closed fractures in skeletally mature individuals. Candidates for ultrasound treatment are those at high risk for delayed fracture healing or nonunion. These risk factors may include either locations of fractures or patient cormorbidities and include the following:" ▪ In Item A 2, added "e) Tibial diaphysis fracture that is closed or grade I open (skin opening is ≤1 cm with minimal muscle contusion)" ▪ In Item B, added "pulsed" to read "Low-intensity pulsed ultrasound treatment may be considered medically necessary as a treatment of delayed union of bones, including delayed union of previously surgically-treated fractures, and excluding the skull and vertebra. (See Policy Guidelines for definition of delayed union.)" ▪ In Item C, added "pulsed" to read "Low-intensity pulsed ultrasound treatment may be considered medically necessary as a treatment of fracture nonunions of bones, including nonunion of previously surgically-treated fractures, and excluding the skull and vertebra. (See Policy Guidelines for definition of nonunion.)" ▪ In Item D, added "pulsed" and "and" to read "Other applications of low-intensity pulsed ultrasound treatment are experimental / investigational, including, but not limited to, treatment of congenital pseudarthroses, open fractures, fresh surgically-treated closed fractures, stress fractures, and arthrodesis or failed arthrodesis." ▪ In Policy Guidelines Item 3 B, removed "3) the fracture gap is 1 cm or less, AND"
	Updated Rationale section.
	Updated References section.

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