Anthem

Clinical UM Guideline

Subject: Ultrasound Bone Growth Stimulation
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Description

This document addresses the use of low-intensity pulsed ultrasound devices as a *non-invasive* treatment to promote healing of some fresh fractures and to accelerate healing for nonunion of other fracture sites.

Note: Please refer to the following document for additional information related to devices used to stimulate bone growth:

- CG-DME-40 Noninvasive Electrical Bone Growth Stimulation of the Appendicular Skeleton

Clinical Indications

Medically Necessary:

A. Fresh Fractures

Non-invasive, low-intensity pulsed ultrasound treatment is considered **medically necessary** for the treatment of fresh fractures when **any** of the following are present:

1. Closed radial fractures, posteriorly displaced (Colles' fracture); **or**
2. Tibial diaphyseal fractures that are either:
    a. Closed; **or**
    b. Grade I open; **or**
3. Closed fracture sites at high risk for nonunion due to:
    a. Location; **and**
    b. Poor vascular supply, for example:
        i. Fractures of the carpal navicular bone (scaphoid fracture); **or**
        ii. 5th metatarsal bone fractures (Jones fracture); **or**
    c. Fractures associated with:
        i. Extensive soft tissue; **or**
        ii. Vascular damage; **or**
4. Closed fractures at high risk for nonunion due to a comorbidity which makes healing likely to be compromised including **any** of the following:
    a. Diabetes; **or**
    b. Renal disease; **or**
    c. Other metabolic diseases; **or**
    d. History of tobacco use; **or**
    e. History of alcoholism; **or**
    f. Nutritional deficiency; **or**
    g. Obese individuals with:
        i. Body Mass Index (BMI) greater than 30; **or**
        ii. When greater than 50% over ideal body weight (IBW);* **or**
    h. Severe anemia; **or**
    i. Steroid therapy.

B. Fracture Nonunions

Non-invasive, low-intensity pulsed ultrasound treatment is considered **medically necessary** when **all** of the following criteria are met:

Feedback

1. Treatment for fracture nonunion of any bone of the appendicular skeleton; **and**
2. At least 45 days have passed since either of the following:
    a. The date of fracture; **or**
    b. The date of appropriate fracture care; **and**
3. No progressive signs of healing have occurred on imaging studies (for example, bony bridging and callus formation); **and**
4. Fracture gap is less than 1 centimeter.

Not Medically Necessary:

Non-invasive, low-intensity pulsed ultrasound treatment is considered **not medically necessary** when the above criteria are not met including, but not limited to, treatment of **any** of the following:

A. As an adjunct to bunionectomy procedures at:
    1. The time of surgery; **or**
    2. Immediately after surgery;** **or**
B. As an adjunct to distraction osteogenesis procedures for any indication, such as:
    1. Limb lengthening; **or**
    2. Nonunion corrective surgery; **or**
    3. Repair of tibial defects at either:
        a. The time of; **or**
        b. Immediately after surgery;** **or**
C. Axial skeleton fractures including:
    1. Skull; **and**
    2. Vertebrae; **or**
D. Congenital pseudoarthrosis; **or**
E. Delayed fracture unions; **or**
F. Fresh open fractures that either:
    1. Require surgical intervention;*** **or**
    2. Are too unstable for closed reduction/casting when either:
        a. Grade II; **or**
        b. Grade III open fractures; **or**
G. Patellar tendinopathy; **or**
H. Pathological fractures due to:
    1. Bone pathology; **or**
    2. Tumor/malignancy; **or**
I. Stress fractures.

Notes:
*See Definitions section for calculation of ideal body weights (IBW).
**When surgical procedures result in nonunion the medically necessary criteria above may apply such as after:

A. Bunionectomy; **or**
B. Distraction osteogenesis.

***Fractures that are nonunion following surgical treatment should be considered for ultrasound bone growth stimulation applying the criteria under Fracture Nonunions in this document.

Coding

The following codes for treatments and procedures applicable to this guideline 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 policy. 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.

When services are Medically Necessary:

CPT	
20979	Low intensity ultrasound stimulation to aid bone healing, noninvasive (nonoperative)

HCPCS	
E0760	Osteogenic stimulator, low intensity ultrasound, noninvasive

ICD-10 Diagnosis	
S52.531A, S52.531D	Colles' fracture of right radius, initial/subsequent encounter for closed fracture
S52.532A, S52.532D	Colles' fracture of left radius, initial/subsequent encounter for closed fracture
S52.539A, S52.539D	Colles' fracture of unspecified radius, initial/subsequent encounter for closed fracture
S82.201A, S82.201D	Unspecified fracture of shaft of right tibia, initial/subsequent encounter for closed fracture
S82.202A, S82.202D	Unspecified fracture of shaft of left tibia, initial/subsequent encounter for closed fracture
S82.209A, S82.209D	Unspecified fracture of shaft of unspecified tibia, initial/subsequent encounter for closed fracture
S82.224A, S82.224D	Nondisplaced transverse fracture of shaft of right tibia, initial/subsequent encounter for closed fracture
S82.225A, S82.225D	Nondisplaced transverse fracture of shaft of left tibia, initial/subsequent encounter for closed fracture
S82.226A, S82.226D	Nondisplaced transverse fracture of shaft of unspecified tibia, initial/subsequent encounter for closed fracture
S82.234A, S82.234D	Nondisplaced oblique fracture of shaft of right tibia, initial/subsequent encounter for closed fracture
S82.235A, S82.235D	Nondisplaced oblique fracture of shaft of left tibia, initial/subsequent encounter for closed fracture
S82.236A, S82.236D	Nondisplaced oblique fracture of shaft of unspecified tibia, initial/subsequent encounter for closed fracture
S82.244A, S82.244D	Nondisplaced spiral fracture of shaft of right tibia, initial/subsequent encounter for closed fracture
S82.245A, S82.245D	Nondisplaced spiral fracture of shaft of left tibia, initial/subsequent encounter for closed fractu
S82.246A, S82.246D	Nondisplaced spiral fracture of shaft of unspecified tibia, initial/subsequent encounter for clo fracture
S82.254A, S82.254D	Nondisplaced comminuted fracture of shaft of right tibia, initial/subsequent encounter for clo fracture
S82.255A, S82.255D	Nondisplaced comminuted fracture of shaft of left tibia, initial/subsequent encounter for close fracture
S82.256A, S82.256D	Nondisplaced comminuted fracture of shaft of unspecified tibia, initial/subsequent encounter closed fracture
S82.264A, S82.264D	Nondisplaced segmental fracture of shaft of right tibia, initial/subsequent encounter for closed fracture
S82.265A, S82.265D	Nondisplaced segmental fracture of shaft of left tibia, initial/subsequent encounter for closed fracture
S82.266A, S82.266D	Nondisplaced segmental fracture of shaft of unspecified tibia, initial/subsequent encounter for closed fracture

When services may be Medically Necessary when criteria are met:
For the procedure codes listed above for all other diagnoses not listed.

When services are Not Medically Necessary:
For the procedure codes listed above when criteria are not met or for situations designated in the Clinical Indications section as not medically necessary.

Discussion/General Information

Evidence in the peer-reviewed published literature in the form of randomized, double-blind, placebo-controlled trials and retrospective case series, and data from a registry of users indicate that low-intensity pulsed ultrasound (also referred to as LIPUS) treatment has been shown to be effective as a treatment to promote healing of fresh distal radius and tibial diaphyseal fractures and to accelerate healing for nonunion of other fracture sites, including the clavicle, humerus, femur, tibia, and the metatarsals and metacarpals. The evidence continues to support the efficacy for these uses, even though a number of systematic reviews, meta-analyses, and a technology assessment have concluded that the evidence is of moderate to low quality and at times appears conflicting. A number of weaknesses are apparent in methodological quality across studies, including difficulty in pooling data because of a paucity of sufficient studies with similar inclusion criteria (such as, heterogeneity of study participants and diversity in the type of bones and fracture location), outcome measures,

type of fracture treatment (that is, conservatively managed versus operatively treated), lack of information about allocation concealment, and inconsistent reporting of acceptable adherence to study protocols (AHRQ, 2005; Bashardoust, 2012; Busse, 2009; Dijkman, 2009; Griffin, 2012; Griffin, 2014; Snyder, 2012).

Low-Intensity Pulsed Ultrasound for Fresh Fractures

The Sonic Accelerated Fracture Healing System (SAHFS®) (Exogen, Inc., West Caldwell, NJ) was initially cleared for marketing by the U.S. Food and Drug Administration (FDA) in October 1994 based on data submitted from two randomized, double-blind, placebo-controlled trials that evaluated low-intensity pulsed ultrasound for the treatment of fresh, closed, posteriorly displaced distal radius (Colles') fractures and fresh, closed, or grade I open tibial diaphyseal fractures in skeletally mature individuals when the fractures are orthopedically managed by closed reduction and cast immobilization (Heckman, 1994; Kristiansen, 1997). These trials demonstrated an acceleration of clinical and radiographic healing in the active treatment groups compared to the control groups.

Additional studies included a randomized, double-blind, placebo-controlled trial conducted in Sweden which examined the efficacy of ultrasound therapy for treating fresh fractures of the tibia in individuals who had surgery, as well as the effects on serum markers of bone regeneration (Emami, 1999). Other studies include two retrospective case series that examined registry data to evaluate the effect of low-intensity pulsed ultrasound on delayed union, fracture nonunion, and fractures in sites other than the tibia and distal radius.

The use of low-intensity pulsed ultrasound stimulation may also be helpful for individuals with closed fresh fractures where the location of the fracture site places it at high risk for subsequent fracture nonunion. Fracture nonunion is more likely to occur in bones with a poor vascular supply, such as the upper thighbone (femoral head and neck), carpal navicular bone (scaphoid fracture), and the fifth metatarsal bone (Jones fracture). Fracture nonunion may also occur in bones with an adequate blood supply, such as a tibial diaphyseal fracture, in the presence of extensive soft tissue or vascular damage as a result of severe trauma to the skin, muscle, and surrounding internal blood supply. Some bones, such as the toe bones, have an excellent blood supply and inherent stability and can be expected to heal without the use of low-intensity pulsed ultrasound therapy.

Closed fresh fractures at high risk for nonunion may also benefit from the use of low-intensity ultrasound therapy in individuals with pre-existing comorbidities. Factors that may increase the risk of nonunion include alcoholism, use of tobacco or nicotine in any form (Cook, 1997), older age, severe anemia, poor nutrition, diabetes, renal disease or other metabolic disorders, and obesity or the presence of infection. Certain medications, including nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, and anticoagulants are also thought to increase risk for nonunion or infection (AHRQ, 2005). There are, however, no randomized controlled studies in the peer-reviewed literature investigating the relationship between NSAIDs and nonunions. Bhattacharyya and colleagues (2005) examined the association between NSAIDs and fracture nonunion in a cohort of 9995 persons with humeral shaft fractures identified from a Medicare database using diagnosis and procedure codes. Of the 9995 humeral shaft fractures, 105 individuals developed nonunions (1.1%), and 1032 (10.3%) were exposed to NSAIDs in the 90 days after fracture. The authors found no relationship between nonselective NSAID use in the first 60 days after humerus fracture and nonunion. The use of NSAIDs 61 to 90 days after fracture was associated with an increased risk of nonunion, but an increased risk was also observed for individuals exposed to opioid analgesics in the same period 61 to 90 days after humerus fracture. The authors concluded:

> The association between NSAIDs and nonunions is complex. Although crude analyses suggest that NSAID exposure is associated with nonunions, analysis of the time course suggests that it is use of NSAIDs late in fracture healing that is most strongly associated with nonunion. Because a similar association is observed with opioids, a drug category without any known effects on fracture healing, it is probable that NSAIDs are being used to treat painful impending nonunions, rather than the NSAIDs causing nonunions.

Lou and colleagues (2017) conducted a meta-analysis to assess the effect of low-intensity pulsed ultrasound for fresh fractures in adults. The literature search included peer reviewed studies from January 1980 through November 2016, and included a total of 12 trials and 1099 participants. The pooled results revealed that low-intensity pulsed ultrasound significantly decreased the time to fracture union (standard mean difference [SMD], 0.65; 95% confidence interval [CI], 1.13 to 0.17), improved the quality of life (SMD, 0.20; 95% CI, 0.03-0.37) without affecting the time to full weight bearing (SMD: 0.76, 95% CI: 1.92 to 0.4), the time to resuming work (SMD, 0.06; 95% CI, 0.14 to 0.27), or the incidence rate of delayed union and nonunion (RR, 1.02; 95% CI, 0.60-1.74).

A subgroup analysis demonstrated that the reduction in healing time with low-intensity pulsed ultrasound was applicable to individuals who were conservatively managed and was not reflected in individuals who underwent surgical intervention.

While the researchers concluded that individuals with fresh fractures may benefit from the use of low-intensity pulsed ultrasound, the authors also noted that there were several methodologic limitations in the trials, including the inadequate concealment of treatment allocation, the high loss of follow-up, the unclear age baseline, smoking or gender status.

To date, there are no randomized studies in the peer-reviewed literature that demonstrate improved outcomes with low-intensity pulsed ultrasound use in individuals on NSAIDs after long bone fracture.

Low-Intensity Pulsed Ultrasound for Fracture Nonunion

In February 2000, the labeled indication for the SAFHS (now known as the Exogen® device) (Smith and Nephew, Inc., Biologics & Spine, Durham, NC) was expanded to include the treatment of established fracture nonunions, excluding the skull and vertebra. According to the FDA labeling, a nonunion is considered to be established when the fracture site shows no visibly progressive signs of healing. The approval was based on prospective studies where individuals served as their own control; in addition, the definition of nonunion suggested that nonunions have a zero percent probability of achieving a healed state without an intervention. The individuals had no recent surgical intervention in order to rule out the possibility of spontaneous healing due to surgery; the only treatment variable was the addition of SAFHS. The submitted data included a small case series (n=74) of individuals with established nonunion with a mean fracture age of nearly 3 years. Individuals with pathologic fractures due to malignancy were excluded from these studies. The principal outcome measure was the percentage of individuals with healed nonunions, as determined clinically and by radiographic analysis. A total of 64 of 74 cases (86%) were healed with the use of low-intensity pulsed ultrasound therapy. The time to healing was 5.6 months. 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 to a healing rate of 95% in those present for no more than 1 year. The FDA Summary of Safety and Effectiveness also cited a case series of 41 nonunions (Nolte, 2001). Of the 29 individuals that completed the study, the average fracture age was 1.2 years. Only 8 individuals had no prior surgery. Of these 8, 7 individuals healed following ultrasound therapy with an average heal time of 157 days, which is similar to those who had surgery (152 days). In this self-paired analysis of pooled data, heal rates for individuals with prior surgery (86%) and no surgery (87.5%) were similar. The authors concluded noninvasive low-intensity pulsed ultrasound therapy can be useful in the treatment of fracture nonunions. Other evidence of the effectiveness of SAFHS for fracture nonunions was obtained from a United States registry of prescription use of the device.

Mayr and colleagues (2000) reported on a retrospective case series (n=153) from a registry of individuals with fracture nonunions without surgery prior to ultrasound stimulation. These individuals had a success rate of 86% (132 of 153) and an average heal time of 140 days after beginning ultrasound therapy. These results are similar to those nonunion cases with surgery prior to ultrasound stimulation (success rate 85%, average heal time of 169 days).

Following the FDA approval, additional published studies reported consistent results. For example, Jingushi and colleagues (2007) analyzed data from a previous multicenter study on low-intensity pulsed ultrasound treatment for postoperative delayed union and nonunion of long bone fractures. Delayed union was defined as more than 3 months without union or radiological bone reaction; nonunion was defined as additional operative treatment being indicated. The study included 72 long bone fractures (42% open, 56% closed) at an average 11.5 months (range: 3 to 68) since the most recent operation. Monthly clinical and radiological evaluation indicated a 75% union rate, with a mean of 219 (range: 56-588) treatment days until union; data for the different subgroups were not reported. There was a significant association with the time of the most recent operation; beginning treatment within 6 months from the most recent operation resulted in a higher union rate (90%) than when treatment was started 12 months after surgery (65%).

Rutten and colleagues (2007) published an analysis of 76 individuals with tibial nonunions. Included in the analysis were 71 individuals who were at least 3 months from the last surgical intervention and did not show any healing improvements in the 3 months before ultrasound treatment (average fracture age: 257 days; range: 180-781). All individuals 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.

Hallux valgus, commonly referred to as a bunion, is a complex group of disorders consisting of a lateral deviation of the great toe, outward angulation of the metatarsal toward the other foot, separation of the heads of the first and second metatarsals, and prominent soft-tissue thickening over the medial surface of the head of the first metatarsal. When conservative measures such as pads and cushions and functional foot orthotics fail to reduce the associated pain or slow the progression of the deformity, surgical correction may be indicated. The choice of surgical procedure is based on a biomechanical and radiographic examination of the foot. A bunionectomy procedure (for example, Akin, Chevron, Keller, Lapidus, or Mitchell metatarsal osteotomy) may be performed to correct a symptomatic hallux valgus by reconstructing the bones and joint to restore normal, pain-free function. The most common bunionectomy procedure performed is the first

metatarsal neck osteotomy, which involves a controlled “surgical fracture” of the bone by cutting and realigning the first metatarsal near the level of the joint; additional procedures may involve soft tissue correction along with concomitant bony correction. Complications following a bunionectomy procedure vary depending on the surgical technique and procedure, including delayed healing of the incision, osseous malunion or nonunion, osteomyelitis, or avascular necrosis. The peer-reviewed medical literature includes prospective, comparative and evaluation studies and retrospective case series reporting low postsurgical complication rates following specific osteotomy procedures for hallux valgus (Dennis, 2011; Enan, 2010; Lee, 2010; Miller, 2011). While there is a lack of published, randomized controlled trials comparing the efficacy of ultrasound bone growth stimulation to sham treatment for postsurgical bunionectomy nonunion, the stimulation device may be a treatment option for individuals to reduce the need for further surgical revision when the individual’s osteotomy site has demonstrated no evidence of progression of healing.

Leighton and colleagues (2017) reported the results of a systematic review and meta-analysis of published literature that explored the use of low-intensity pulsed ultrasound as a treatment of nonunions. A total of 13 eligible papers, (including one randomized controlled trial) reporting the results of low-intensity pulsed ultrasound for the treatment of 1441 nonunions of the tibia, humerus, radius, ulna and femur, were evaluated. The date range of the literature search was not specified. The quality of the studies was scored using the Methodological Index for Non-Randomized Studies. Quality scores ranged from 5 to 12 (with an “ideal” score for a nonrandomized trial being 16). While the pooled estimate of effect size for the healing rate was 82% (95% CI, 77% to 87%), for any anatomical site and a fracture of at least 3 months duration. significant heterogeneity was identified. Another analysis which excluded studies with quality scores of 6 or lower, revealed a comparable heal rate of 80% (95% CI, 74% to 85%). Because some participants in the analysis were treated with conservative measures and others underwent surgical interventions, the researchers did not recommend LIPUS instead of surgery for all nonunions. Instead, the authors concluded that LIPUS might be useful in individuals for whom surgery is high risk.

Low-Intensity Pulsed Ultrasound for other Conditions

There are no controlled studies in the published literature that specifically address the use of low-intensity pulsed ultrasound as a treatment of fresh fractures of the axial skeletal system, fractures due to bone malignancy, congenital pseudoarthroses, or as an adjunct to spinal fusion. There are no studies in the peer-reviewed literature specifically focused on improved healing rates following uncomplicated bunionectomy procedures (first metatarsal osteotomy) as compared to a period of immobilization and limited weight bearing; in addition, these surgeries are not considered at high risk for post-surgical nonunion.

Open Fractures and Distraction Osteogenesis

Data is also conflicting regarding the efficacy of low-intensity pulsed ultrasound for the treatment of open fractures, specifically those treated surgically with placement of an intramedullary nail. Emami and colleagues (1999) conducted a study that randomized 32 individuals with a fresh tibial fracture that was fixed with an intramedullary rod to undergo additional treatment with an active or inactive ultrasound device. The time to healing was not significantly different in the 2 groups. These observations are consistent with a meta-analysis conducted by Busse and colleagues (2002) whose analysis supported the use of low-intensity pulsed ultrasound as a technique for fractures treated nonoperatively. However, the authors concluded that there was no benefit in operatively treated fractures. In contrast, Leung and colleagues (2004) reported on the results of a randomized, prospective study of 30 fractures in 28 individuals with complex tibial fractures treated with internal or external fixation to receive or not receive additional treatment with low-intensity pulsed ultrasound. Based on radiologic assessment, the time to callus formation was significantly less in those in the ultrasound treatment group; however, 2 individuals in the control group experienced delayed union (12%). Due to the inconsistent results in these two small, randomized studies, and the negative results of the meta-analysis, low-intensity pulsed ultrasound is still considered not medically necessary for open fractures.

El-Mowafi and Mohsen (2005) applied low-intensity pulsed ultrasound on 21 participants with tibial defects (range, 5 cm to 8 cm) with distraction osteogenesis using an Ilizarov external fixator. A total of 10 participants received 20 minutes of low-intensity pulsed ultrasound stimulation daily on the bone lengthening site (Group A) while rigid fixation was maintained in the remaining participants (Group B). All participants were followed with weekly radiographs to determine the formation of an external cortex and an intramedullary canal, at which time the fixator was removed. The mean healing index in Group A was reported at 30 (range: 27 to 36) days/centimeter (cm) compared to 48 (range: 42 to 75) days/cm in Group B. One participant in Group B failed to consolidate the regenerated bone. The investigators suggested that low-intensity pulsed ultrasound stimulation was highly effective in achieving maturation of bone and reducing time of distraction osteogenesis. Limitations of this study include the small sample size and heterogeneity of the study participants, in that distraction osteogenesis was performed as primary management in 4 participants (2 participants with open fractures and 2

participants with congenital anterolateral bowing of the tibia) while the remaining participants were treated after development of nonunion.

Dudda and colleagues (2011) investigated the effect of low-intensity pulsed ultrasound in a prospective randomized controlled trial of 36 participants (n=16 treatment group, n=20 control group) who underwent distraction osteogenesis (> 2 cm) to the lower extremities. The authors did not specify the location of the bone distraction beyond “right” and “left” lower leg” in either the treatment or control group. Fixation devices included Regazzoni, Ilizarov, and hybrid fixators. Evaluation was performed by standard radiographs every 3 to 4 weeks. Treatment outcomes were reported in measures of the length of the “fixator gestation period”, the distraction consolidation index (the ratio of fixator gestation time in days over the distraction gap size in cm), and the Paley index (ratio of fixator gestation period in months over the distraction gap size in cm). The investigators reported a shorter fixation gestation period by 43.6 days for the treatment group versus the control group, 218.6 versus 262.2 days, respectively, but the statistical significance of this outcome was not reported. The mean distraction consolidation index for the treatment group was 32.8 days/cm and 44.6 days/cm for the control group (p=0.116). The mean Paley index for the treatment versus the control group was 1.09 months/cm and 1.49 months/cm, respectively (p=0.116). The difference between the treatment and control groups in these measures did not reach statistical significance. Limitations of this study include the small number of callus distractions performed, heterogeneity of the population (highly variable patterns of injury and medical treatments performed), and the lack of blinding to treatment.

Salem and colleagues (2014) evaluated the use of low-intensity pulsed ultrasound to no treatment (controls) in a nonblinded, randomized trial of 21 individuals undergoing callus distraction for posttraumatic tibial defects. An Ilizarov ring fixator was used in all cases. Outcomes were examined clinically and radiologically, analyzing callus maturation with a computer-assisted measurement. Use of low-intensity pulsed ultrasound shortened healing by 12 days/cm and the total fixator time by 95 days. The results of this study are limited by the small number of participants and nonblinded study design. Larger randomized, sham-controlled trials of homogeneous study populations are needed to evaluate the efficacy of low-intensity pulsed ultrasound as an adjunct to distraction osteogenesis procedures for any indication.

Stress Fractures

Low-intensity pulsed ultrasound has been studied for accelerating healing of stress fractures. In a prospective, randomized, double-blind clinical trial, Rue and colleagues (2004) studied if low-intensity pulsed ultrasound therapy reduces tibial stress fracture healing time. A total of 26 midshipmen (43 tibial stress fractures) were randomized to receive ultrasound therapy or placebo treatment. Twenty-minute daily treatments continued until the individuals were asymptomatic with signs of healing on plain radiographs. The groups were not significantly different in demographics, delay from symptom onset to diagnosis, missed treatment days, total number of treatments, or time to return to duty. Findings of this study demonstrated that low-intensity pulsed ultrasound did not significantly reduce the healing time for tibial stress fractures.

Gan and colleagues (2014) evaluated the effectiveness of low-intensity pulsed ultrasound for the improvement of lower limb bone stress injuries in a civilian population. In this prospective, randomized, double-blind, placebo-controlled trial, individuals with a magnetic resonance imaging (MRI)-diagnosed grade II-IV bone stress injury of either the postero-medial tibia, fibula or second, third, or fourth metatarsal were randomized to either active treatment or placebo device for 20 minutes daily for 4 weeks. A total of 30 participants were initially recruited; 23 participants were included in the final analysis. Six clinical parameters including night pain, pain at rest, pain on walking, pain with running, tenderness, and pain with single leg hop were compared prior to and after the intervention. The investigators reported no significant differences between the treatment and placebo groups for measurements of the six clinical parameters. Regardless of the relatively short duration of 4 weeks and the small sample size consisting of primarily female participants, low-intensity pulsed ultrasound was found to be ineffective for the healing of lower limb bone stress injuries.

Sesamoid Fractures

A sesamoid is a bone entrenched in a tendon. Sesamoids are found in several joints in the body including the knee (patella), the hands (metacarpals) and the feet (metatarsals). Treatment options for sesamoid fractures vary depending on the anatomical location and fracture type (e.g. stress, displaced); however, a review of the peer-reviewed, scientific literature does not reveal any studies investigating the use of low-intensity puled ultrasound as a treatment of sesamoid fractures. At this time, there is insufficient evidence to draw conclusions about the safety or efficacy of low-intensity pulsed ultrasound to assist with the healing of sesamoid fractures.

Clavicle Fractures

The effect of low-intensity pulsed ultrasound on the healing of fresh clavicle fractures was studied in a multicenter, randomized, double-blind, placebo-controlled trial of 120 adults with a non-operatively treated fresh clavicle shaft fracture;

data were analyzed on an intention-to-treat basis (Lubbert, 2008). The primary outcome measure was subjective fracture healing from clinical symptoms, including pain, range of motion and local instability at the fracture site as reported by the participant. The investigators refrained from the use of radiological evidence of fracture healing, citing the development of visible callus on radiographs is “not always related to clinical signs of fracture healing.” Secondary outcome measures were possible operation, painkiller use, pain (Visual Analogue Scale [VAS]), adverse events, and resumption of sport and professional or household activities. A total of 9 participants in the active treatment group and 10 in the placebo group were excluded from the analysis because of incomplete follow-up or early withdrawal from the study. The day that the fracture clinically healed according to participant perception was determined in 92 participants (47 active treatment; 45 placebo); mean duration time to clinical healing was 26.77 days in the active treatment group versus 27.09 days in the placebo group (mean difference 0.33, p=0.91). Between-group differences in analgesic use (37.21 tablets, active treatment and 32.88 tablets, placebo group; mean difference 4.34, p=0.66) and mean VAS (3.51 active treatment, 3.55 placebo group; mean difference 0.04, p=0.90) were not significant. The investigators concluded that the time to clinical healing of fresh clavicle shaft fractures in the study was not influenced by low-intensity pulsed ultrasound treatment, however, “refraining from radiological appraisal of fracture healing… makes comparison with previous studies difficult.” A subsequent Cochrane review confirmed “there is insufficient evidence from randomized controlled trials to determine which methods of conservative treatment (including therapeutic ultrasound) are the most appropriate for acute middle third clavicle fractures in adolescents and adults” (Lenza, 2009).

Delayed Union of Tibial Shaft Fractures

In a multicenter, randomized, sham-controlled, industry-sponsored trial, Schofer and colleagues (2010) compared the healing response of tibial shaft fractures (delayed union) between participants treated with either low-intensity pulsed ultrasound (n=51) with the Exogen 2000/2000+ or a sham device (n=50). Delayed union was defined as lack of clinical and radiologic evidence of union, bony continuity or bone reaction at the fracture site for no < 16 weeks from the index injury or the most recent intervention. The primary outcome with respect to efficacy (progress to healing) was change in bone mineral density (BMD) as assessed by computed tomography (CT) scans between pre-treatment and 16 weeks. The secondary endpoint was change in gap area at the fracture site. Standard anteroposterior (AP) and lateral radiographs were taken at 1-, 2- and 3-month follow-up intervals. A total of 17 participants had missing post-treatment outcomes; therefore, 84 participants were included in descriptive analyses of ‘completers.’ There were notable differential dropout rates between groups with 24% (12 of 50) of sham-treated participants and 9.8% (5 of 51) of active-treated participants missing post-treatment BMD values. Despite such a high number of dropouts in the sham group, the overall healing rate in that group was not significantly different from the active treatment group (p=0.07, 46% [23 of 50] of sham to 65% [33 of 51] of active treatment), even though the sham group had a significantly higher body mass than the active treatment group, and body mass is a risk factor for nonunion. Further studies with larger, homogeneous populations are warranted to determine the treatment effect of low-intensity pulsed ultrasound on improving healing rates in individuals with delayed fracture union.

Patellar Tendinopathy

Larsson and colleagues (2012) conducted a systematic review of the published randomized controlled trials comparing treatments for patellar tendinopathy. The authors stated low-intensity pulsed ultrasound did not provide any additional benefit over and above placebo in the management of symptoms associated with patellar tendinopathy. This conclusion was based on the results of a small randomized, double-blind, placebo-controlled trial (n=37) measuring changes in “usual” and “worst” tendon pain during the participant's most aggravating activity in the preceding week (Warden, 2008).

Upper Extremity Osteotomy Sites

Urita and colleagues (2013) conducted a small, quasi-randomized study (alternating assignment) of 27 individuals treated with low-intensity pulsed ultrasound after ulnar shortening osteotomy for ulnar impaction syndrome or radial shortening osteotomy for Kienbock disease. Participants in the low-intensity pulsed ultrasound group received once daily 20-minute treatments for at least 12 weeks postoperatively. Blinded evaluation of radiographic healing showed that low-intensity pulsed ultrasound reduced the mean time to cortical union by 27% (57 vs. 76 days) and endosteal union by 18% (121 vs. 148 days). The two groups had similar results on the Modified Mayo Wrist Score and no pain at the osteotomy site at the time of endosteal healing (mean, 121 or 148 days). Limitations of this study include the small sample size, lack of a sham control, and the long interval between the 16-week and 24-week assessments, which may have increased group differences. Additional study is needed to determine the effect of low-intensity pulsed ultrasound on healing of upper extremity osteotomy sites.

Failed Arthrodesis

Mirza and colleagues (2019) reported the results of a retrospective observational study reviewing the use of low-intensity pulsed ultrasound in participants who had arthrodesis of a variety of foot and ankle joints diagnosed with delayed or non-union. Over a period of 5 years, a total of 18 participants (7 1st metatarsophalangeal joint, 2 subtalar joint, 2 triple fusions, 4 ankle and 3 isolated midfoot joint fusions) with radiologically confirmed delayed union, were treated with a standardized low-intensity pulsed ultrasound therapy. Twelve participants (67%) were confirmed by radiology to have been treated successfully. Additional surgical revision was required in 4 participants while 2 individuals were treated conservatively. A higher incidence of fusion was seen in small foot joints (9/10; 90%) versus larger or multiple joint arthrodesis (3/8; 38%) following low-intensity pulsed ultrasound. While the authors concluded that there may be a role for the use of low-intensity pulsed ultrasound as a treatment for delayed union of isolated, small foot joint arthrodesis, they did not recommend its use in large or multiple foot and ankle joint arthrodesis. Additional studies including large multicenter trials are required to confirm these findings.

Definitions

Appendicular skeleton: Composed of bones of the upper and lower limbs, and the bones that anchor the upper and lower limbs to the axial skeleton:

- upper extremities (humerus, radius, ulna, carpal, metacarpal, and phalange bones)
- lower extremities (femur, tibia, fibula, patella, tarsal, metatarsal, and phalange bones)
- shoulder or pectoral girdle (clavicle and scapula bones)
- pelvic or hip girdle

Axial skeleton: Composed of bones that form the axis of the body and support and protect the organs of the head, neck, and trunk; includes the ribs, skull, sternum and vertebral column (including the coccyx and sacrum).

Bunionectomy: A surgical procedure to remove a bony bump (bunion) of the foot and realign the big toe (great toe).

Delayed/incomplete fracture union: A fracture that has not healed in the time frame that would be considered normal for a specific type of fracture considering an individual's unique medical condition, despite ongoing evidence of bone growth activity. The decelerated healing process of a fracture as determined by serial radiographs or appropriate imaging studies.

Distraction osteogenesis (DO): A procedure that moves two segments of a bone slowly apart in such a way that new bone fills in the gap.

Flat bones: Bones that are thin and have broad surfaces; include the scapula, ribs, and the sternum (breastbone).

Fracture nonunion: A fracture in which all evidence of bone growth activity at the fracture site has ceased, leaving a persistent unhealed fracture of the bone.

Fresh fracture: A fracture that has recently occurred, typically considered ≤ 7 days in duration, and has not had previous treatment, other than emergency splinting prior to evaluation and fixation.

Hallux valgus deformity (bunion): A medial deviation of the first metatarsal and lateral deviation and/or rotation of the hallux, with or without medial soft-tissue enlargement of the first metatarsal head. This condition can lead to painful motion of the joint or difficulty with footwear.

Ideal body weight (IBW): Obesity has been defined as anyone who is 50% over their ideal body weight. The ideal body weight is calculated according to the following formula (**Note:** 1kg = 2.2 lbs):

- Females: IBW = 45.5 kg + 2.3 kg for each inch over 5 feet
- Males: IBW = 50 kg + 2.3 kg for each inch over 5 feet

Long bones: Bones found in the extremities comprised of a shaft (diaphysis) and 2 ends (epiphyses); includes the humerus, radius, ulna, femur, tibia, fibula, metatarsal, and metacarpal bones.

Osteotomy: A surgical procedure where a bone or segment of a bone is cut or removed, realigned, and allowed to heal in its new position; most often, performed to realign a deformed bone.

Pseudoarthrosis: A condition where a bone fracture has healed with fibrous material instead of bone tissue; also referred to as pseudarthrosis or a "false joint."

Sesamoid bones: An ovoid, nodular mass of bone or cartilage within a tendon or joint capsule, principally in the hands and lower extremities; the patella is the largest sesamoid bone in the body.

Short bones: Bones with a tubular shaft and articular surfaces at each end but much smaller in size; includes all of the metacarpals and phalanges in the hands, the metatarsals and phalanges in the feet, and the clavicle (collarbone).

Stress fractures: Microscopic tears or cracks in bones caused by repetitive (rather than sudden) mechanical stress.

Tibial diaphysis: Refers to the shaft of the tibia, also known as the shin bone.

Ultrasound bone growth stimulator: A medical device that uses low-intensity pulsed ultrasound energy to stimulate bone growth.

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Exogen 2000™
Exogen 2000+™
Exogen 3000™
Exogen 4000+
Exogen Pulsed Low-Intensity Bone Healing System
SAFHS Model 2000

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
Revised	05/08/2025	Medical Policy & Technology Assessment Committee (MPTAC) review. In MN criteria: (1) Added blank line above criteria set B - Fracture Non-unions; (2) Added ":" at the end of the first sentence in criteria set B; and (3) In criterion B-1, deleted extra space after the word "appendicular". Revised Discussion/General Information, References and Websites for Additional Information sections.
Reviewed	05/09/2024	MPTAC review. Updated References and Websites for Additional Information sections.
Reviewed	05/11/2023	MPTAC review. Updated References and Websites for Additional Information sections.
Revised	02/16/2023	MPTAC review. Revised formatting and made minor language revisions to MN and NMN criteria.
Reviewed	05/12/2022	MPTAC review. Updated Discussion/General Information, References and Website for Additional Information sections.
Reviewed	05/13/2021	MPTAC review. Updated References and Websites for Additional Information sections. Reformatted Coding section.
Reviewed	05/14/2020	MPTAC review. Updated References and Websites for Additional Information sections.
Revised	06/06/2019	MPTAC review. In the medically necessary statement, bullet "3a", clarified what is meant by "location and poor vascular supply". Updated Discussion/General Information, Definitions, References and Websites for Additional Information sections.
New	07/26/2018	MPTAC review. Initial document development. Moved content of DME.00027 Ultrasound Bone Growth Stimulation to new clinical utilization management guideline document with the same title.

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the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.