Medical Policy

Subject: Ultrasound Bone Growth Stimulation
Policy #: DME.00027
Current Effective Date: 10/06/2015
Status: Reviewed
Last Review Date: 08/06/2015

Description/Scope
This document addresses the use of low-intensity pulsed ultrasound devices as a 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:
- DME.00004 Electrical Bone Growth Stimulation

Position Statement
Medically Necessary:

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'); or
2. Tibial diaphyseal fractures, closed or Grade I open; or
3. Closed fracture sites at high risk for nonunion due to:
   - location and poor vascular supply (for example, carpal navicular/scaphoid fractures, Jones/5th metatarsal fracture); or
   - fractures associated with extensive soft tissue or vascular damage; or
4. Closed fractures at high risk for nonunion due to a comorbidity which includes any of the following:
   - Diabetes, renal disease, or other metabolic diseases where bone healing is likely to be compromised; or
   - History of tobacco use or alcoholism; or
   - Nutritional deficiency; or
   - Obese individuals with a Body Mass Index (BMI) greater than 30 or who are greater than 50% over their ideal body weight (IBW) (Note: See Definition section for calculation of IBW); or
   - Severe anemia; or
   - Steroid therapy.

Fracture Nonunions
Non-invasive, low-intensity pulsed ultrasound treatment is considered medically necessary for the treatment of fracture nonunion of bones of the appendicular skeleton (clavicle, humerus, radius, ulna, femur, fibula, tibia, carpal, metacarpal, tarsal, or metatarsal) when all of the following criteria are met:

- At least 45 days have passed since the date of fracture or appropriate fracture care; and
- Serial radiographs or appropriate imaging studies confirm there is no evidence of progression of healing; and
- Fracture gap is less than 1 centimeter.

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

- As an adjunct to (at the time of or immediately after) bunionectomy procedures (Note: When such surgery results in nonunion the medically necessary criteria above may apply); or
- As an adjunct to (at the time of or immediately after) distraction osteogenesis procedures for any indication (for example, limb lengthening, nonunion, or tibial defects); or
- Axial skeleton fractures, including the skull and vertebrae; or
- Congenital pseudarthrosis; or
- Delayed fracture unions; or
- Fresh fractures that are Open Grade II or III, or require surgical intervention (with or without internal fixation), or are otherwise too unstable for closed reduction/casting (Note: Fractures that are nonunion and have undergone surgical treatment and no longer require surgical intervention should be considered for ultrasound bone growth stimulation applying the criteria in Fracture Nonunions); or
- Patellar tendinopathy; or
- Pathological fractures due to bone pathology or tumor/malignancy; or
- Stress fractures.

Rationale
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.

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 had 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 primarily 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 the mean healing (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 tibia 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 bunectomy 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 bunectomy 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 bunectomy procedure vary depending on the surgical technique and procedure, including, but are not limited to 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 no evidence of progression of healing.

**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 bunectomy 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 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 postoperative 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 2 small randomized studies, and the negative results of the meta-analysis, low-intensity pulsed ultrasound is still considered investigational and not medically necessary for open fractures.

El-Mowafi and Mohsen (2005) applied low-intensity pulsed ultrasound on 21 subjects with tibial defects (range: 5 cm to 8 cm) with distraction osteogenesis using an Ilizarov external fixator. Ten subjects 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 subjects (Group B). All subjects 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/cm compared to 48 (range: 42 to 75) days/cm in Group B. One subject 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 subjects (2 subjects with open fractures and 2 subjects with congenital anterolateral bowing of the tibia) while the remaining subjects 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-pulsed intensity 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-pulsed intensity 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-pulsed intensity 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 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 6 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.

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 subjects 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 subjects had missing post-treatment outcomes; therefore, 84 subjects were included in descriptive analyses of 'complete.' There were notable differential dropout rates between groups with 24% (12 of 50) of sham-treated subjects and 9.8% (5 of 51) of active-treated subjects 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

https://www.bcbsga.com/medicalpolicies/policies/mp_pw_a050287.htm
Ultrasound bone growth stimulation is delivered by a noninvasive, low-intensity pulsed ultrasound device that provides nonthermal, high-frequency acoustic pressure waves to accelerate healing of fresh fractures and to promote healing of fracture nonunions that are unresponsive to standard fracture treatment. The device is characterized by a main operating unit, with an external power supply, that is connected to a treatment head module, which is affixed to a mounting fixture that is centered over the fracture site. The device is intended for use by the individual in the home setting in one daily 20-minute treatment until healing is confirmed.

Ultrasound bone growth stimulators receive premarket approval (PMA) by the FDA as class III devices. Since the original PMA for the SAFHS Model 2A, supplemental approvals have been granted by the FDA for various changes incorporated into the design and manufacture of the device, as well as a labeling change to the trade name of the device used to treat nonunions to the Exogen 4000+™ (FDA, 2008). According to the manufacturer's package insert (dated March 27, 2009), there are no known contraindications to the use of the device. The safety and effectiveness of the device has not been established for use in fracture nonunions of the vertebra and the skull, and for use in individuals with fractures with the following: fracture locations other than the distal radius or tibial diaphysis; fractures with post-reduction displacements of more than 50%; fractures that are open Grade II or III or that require surgical intervention or with internal or external fixation or that are not sufficiently stable for closed reduction and cast immobilization; pathological fractures due to bone pathology or malignancy; individuals with thrombophlebitis, vascular insufficiency, abnormal skin sensitivity, sensory paralysis, alcoholism and/or nutritional deficiency; and those receiving steroid, anticoagulant, prescription nonsteroidal anti-inflammatory, calcium channel blocker and/or diphosphonate therapy. These contraindications were excluded from the clinical studies because of their possible effects on bone metabolism. Individuals who lack skeletal maturity, pregnant or nursing women, and those with active, implantable devices, such as cardiac pacemakers are not candidates for use of the device. Use of the device is not indicated for more than one daily 20-minute treatment period.

### 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; includes 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 nonunion (bone fragments). 

**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.

---

[https://www.bcbsga.com/medicalpolicies/policies/mp_pw_a050287.htm](https://www.bcbsga.com/medicalpolicies/policies/mp_pw_a050287.htm)
Ultrasound bone growth stimulation: A medical device that uses low-intensity pulsed ultrasound energy to stimulate bone growth.

**Coding**

The following codes for treatments and procedures applicable to this document 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**

<table>
<thead>
<tr>
<th>Code</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>

**HCPCS**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E0760</td>
<td>Osteogenic stimulator, low intensity ultrasound, noninvasive</td>
</tr>
</tbody>
</table>

**ICD-10 Diagnosis**

[For dates of service on or after 10/01/2015]

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>S52.511A, S52.51D</td>
<td>Colles’ fracture of right radius, initial/subsequent encounter for closed fracture</td>
</tr>
<tr>
<td>S52.522A, S52.532D</td>
<td>Colles’ fracture of left radius, initial/subsequent encounter for closed fracture</td>
</tr>
<tr>
<td>S52.539A, S52.539D</td>
<td>Colles’ fracture of unspecified radius, initial/subsequent encounter for closed fracture</td>
</tr>
<tr>
<td>S82.201A, S82.201D</td>
<td>Unspecified fracture of right tibia, initial/subsequent encounter for closed fracture</td>
</tr>
<tr>
<td>S82.202A, S82.202D</td>
<td>Unspecified fracture of left tibia, initial/subsequent encounter for closed fracture</td>
</tr>
<tr>
<td>S82.209A, S82.209D</td>
<td>Unspecified fracture of right tibia, initial/subsequent encounter for closed fracture</td>
</tr>
<tr>
<td>S82.224A, S82.224D</td>
<td>Nondisplaced transverse fracture of right tibia, initial/subsequent encounter for closed fracture</td>
</tr>
<tr>
<td>S82.225A, S82.225D</td>
<td>Nondisplaced transverse fracture of left tibia, initial/subsequent encounter for closed fracture</td>
</tr>
<tr>
<td>S82.226A, S82.226D</td>
<td>Nondisplaced transverse fracture of unspecified tibia, initial/subsequent encounter for closed fracture</td>
</tr>
<tr>
<td>S82.234A, S82.234D</td>
<td>Nondisplaced oblique fracture of right tibia, initial/subsequent encounter for closed fracture</td>
</tr>
<tr>
<td>S82.235A, S82.235D</td>
<td>Nondisplaced oblique fracture of left tibia, initial/subsequent encounter for closed fracture</td>
</tr>
<tr>
<td>S82.236A, S82.236D</td>
<td>Nondisplaced oblique fracture of unspecified tibia, initial/subsequent encounter for closed fracture</td>
</tr>
<tr>
<td>S82.244A, S82.244D</td>
<td>Nondisplaced spiral fracture of right tibia, initial/subsequent encounter for closed fracture</td>
</tr>
<tr>
<td>S82.245A, S82.245D</td>
<td>Nondisplaced spiral fracture of left tibia, initial/subsequent encounter for closed fracture</td>
</tr>
<tr>
<td>S82.246A, S82.246D</td>
<td>Nondisplaced spiral fracture of unspecified tibia, initial/subsequent encounter for closed fracture</td>
</tr>
<tr>
<td>S82.254A, S82.254D</td>
<td>Nondisplaced comminuted fracture of right tibia, initial/subsequent encounter for closed fracture</td>
</tr>
<tr>
<td>S82.255A, S82.255D</td>
<td>Nondisplaced comminuted fracture of unspecified tibia, initial/subsequent encounter for closed fracture</td>
</tr>
<tr>
<td>S82.264A, S82.264D</td>
<td>Nondisplaced segmental fracture of right tibia, initial/subsequent encounter for closed fracture</td>
</tr>
<tr>
<td>S82.265A, S82.265D</td>
<td>Nondisplaced segmental fracture of left tibia, initial/subsequent encounter for closed fracture</td>
</tr>
<tr>
<td>S82.266A, S82.266D</td>
<td>Nondisplaced segmental fracture of unspecified tibia, initial/subsequent encounter for closed fracture</td>
</tr>
</tbody>
</table>

**ICD-9 Procedure**

[For dates of service prior to 10/01/2015]

99.86 | Non-invasive placement of bone growth stimulator [when specified as ultrasonic] |

**ICD-9 Diagnosis**

[For dates of service prior to 10/01/2015]

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>813.41</td>
<td>Colles’ fracture, closed</td>
</tr>
<tr>
<td>813.42</td>
<td>Other fractures of distal end of radius (closed)</td>
</tr>
<tr>
<td>814.01</td>
<td>Fracture of carpal bone, closed, navicular [scaphoid] of wrist</td>
</tr>
<tr>
<td>823.20</td>
<td>Fracture of tibia shaft, closed</td>
</tr>
<tr>
<td>825.25</td>
<td>Fracture of metatarsal bone(s), closed</td>
</tr>
</tbody>
</table>

**When services may be Medically Necessary when criteria are met**

For the procedure codes listed above, for the following diagnoses:

**ICD-10 Diagnosis**

[For dates of service on or after 10/01/2015]

All other applicable fracture or fracture nonunion diagnoses

**ICD-9 Diagnosis**

[For dates of service prior to 10/01/2015]

733.82 | Nonunion of fracture |
| 807.00-809.1 | Fracture of rib(s), sternum, larynx and trachea, pelvis, trunk |

https://www.bcbsga.com/medicalpolicies/policies/mp_pw_a050287.htm
When services are Investigational and Not Medically Necessary:
For the procedure codes listed above when criteria are not met; or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

References

Peer Reviewed Publications:

34. Urita A, Iwasaki N, Kondo M, et al. Effect of low-intensity pulsed ultrasound on bone healing at osteotomy sites after

https://www.bcbsga.com/medicalpolicies/policies/mp_pw_a050287.htm


Government Agency, Medical Society, and Other Authoritative Publications:


Websites for Additional Information


Index

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.

Document History

<table>
<thead>
<tr>
<th>Status</th>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reviewed</td>
<td>08/06/2015</td>
<td>Medical Policy &amp; Technology Assessment Committee (MPTAC) review. Updated Rationale and References sections.</td>
</tr>
<tr>
<td>Reviewed</td>
<td>08/14/2014</td>
<td>MPTAC review. Minor format changes throughout document. Updated Rationale, References, and Websites for Additional Information sections.</td>
</tr>
<tr>
<td>Revised</td>
<td>08/08/2013</td>
<td>MPTAC review. Clarified medically necessary statement for closed, fresh fractures at high risk for nonunion due to a comorbid condition. Minor format revisions to text. Updated Rationale and Reference sections.</td>
</tr>
<tr>
<td>Revised</td>
<td>08/09/2012</td>
<td>MPTAC review. Clarified medically necessary statement for closed fractures at high risk for nonunion due to a comorbid condition. Clarified the investigational and not medically necessary statement and added distraction osteogenesis procedures and patellar tendinopathy. Updated Rationale, Definitions, Coding, References, Websites for Additional Information and Index.</td>
</tr>
<tr>
<td>Revised</td>
<td>08/18/2011</td>
<td>MPTAC review. Clarified investigational and not medically necessary statement for bunionectomy procedures, defining &quot;as an adjacent to&quot; and adding a Note when to refer to the Fracture Nonunion criteria. Updated Rationale, Definitions, References and Websites for Additional Information.</td>
</tr>
<tr>
<td>Revised</td>
<td>08/19/2010</td>
<td>MPTAC review. Revised medically necessary criteria for Fresh Fractures, adding Body Mass Index (BMI) greater than 30 as an index to determine when an individual is considered obese (comorbid risk factor); for Fracture Nonunions, clarified and reworded statement for the types of bones that may be eligible for low-intensity pulsed ultrasound therapy if criteria are met. Revised order of the criteria in the investigational and not medically necessary statement; added &quot;axial skeleton fractures, including the skull and vertebrae&quot; (moved from medically necessary statement &quot;excluding the skull or vertebrae&quot;). Updated Description, Rationale, Background, Definitions, References and Index. Added section for Websites for Additional Information.</td>
</tr>
<tr>
<td>Revised</td>
<td>08/27/2009</td>
<td>MPTAC review. Revised title to Ultrasound Bone Growth Stimulation. Clarified medically necessary statement and criterion for fresh fractures, including those at high risk for nonunion; added a Note to criterion for obese patients with reference to a definition for calculation of ideal body weight. Revised medically necessary criteria for fracture nonunion: 1) deleted criterion referencing the investigational and not medically necessary criteria; 2) added criterion addressing the size of the fracture gap, i.e. &quot;the fracture gap is less than 1 centimeter.&quot; Revised investigational and not medically necessary criteria: 1)</td>
</tr>
</tbody>
</table>
deleted "a bone gap greater than one half the diameter of the bone at the point of nonunion, 2) fresh fractures that are Open Grade II or III or require surgical intervention, 3) fractures involving immature skeletal systems, 4) clarified pathological fracture criterion, 5) added criterion "as an adjunct to bunionectomy," 6) removed "Skeletal maturity definition. Updated Rationale, Definitions, Coding and References.

Revised 11/20/2008
MPTAC review. Addition of specific fracture locations to the medically necessary, fresh fracture position statement: 3) Fracture sites at high risk for nonunion due to: location and poor vascular supply (e.g. carpal navicular/scaphoid fractures, Jones/5th metatarsal fracture); fractures associated with extensive soft tissue or vascular damage; Clarified medically necessary criteria for fracture nonunions and added "appropriate imaging studies" to "Serial radiographs or appropriate imaging studies confirm that no progressive signs of healing have occurred."

Clarified investigational and not medically necessary criteria: The word "Fresh" and a Note statement were added to the 4th bullet: Fresh fractures that are Open Grade II or III, or require surgical intervention; with or without internal fixation), or are otherwise too unstable for closed reduction/casting (Note: Fractures that are nonunion and have undergone surgical treatment and no longer require surgical intervention should be considered for UBGSt applying the criteria in Fracture Nonunions). Updated Discussion, Rationale, Coding, and References.

Revised 05/15/2008
MPTAC review. Clarified position statement for fracture nonunions. In the medically necessary criteria, deleted "...date of surgical treatment of the fracture" from the first bullet "At least 45 days have passed since the date of fracture..." Updated References.

Revised 11/29/2007
MPTAC review. Clarified position statement for fresh fractures, revised high risk/comorbidities criteria. Aligned treatment of fracture nonunions with DME.00004 Electrical Bone Growth Stimulation. Addition of investigational/not medically necessary criteria for: a bone gap greater than one half the diameter of the bone at the point of nonunion; pathological fractures due to bone pathology or malignancy; and for stress fractures. Reformatted and updated Description, Rationale, Background, Definitions, and References. The phrase "investigational/not medically necessary" was clarified to read "investigational and not medically necessary."

Reviewed 03/08/2007
MPTAC review. Updated References.

Reviewed 03/23/2006
MPTAC review. Updated References.

Revised 04/28/2005
MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization.

Pre-Merger Organizations
WellPoint Health Networks, Inc.

Last Review Date 03/01/2004
Document Number 2.07.04
Title Ultrasonic Bone Growth Stimulation

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

© CPT Only – American Medical Association