Horizon BCBSNJ
Uniform Medical Policy Manual

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Subject:
Ultrasound Accelerated Fracture Healing Device

Description:

IMPORTANT NOTE:

The purpose of this policy is to provide general information applicable to the administration of health benefits that Horizon Blue Cross Blue Shield of New Jersey and Horizon Healthcare of New Jersey, Inc. (collectively "Horizon BCBSNJ") insures or administers. If the member's contract benefits differ from the medical policy, the contract prevails. Although a service, supply or procedure may be medically necessary, it may be subject to limitations and/or exclusions under a member's benefit plan. If a service, supply or procedure is not covered and the member proceeds to obtain the service, supply or procedure, the member may be responsible for the cost. Decisions regarding treatment and treatment plans are the responsibility of the physician. This policy is not intended to direct the course of clinical care a physician provides to a member, and it does not replace a physician's independent professional clinical judgment or duty to exercise special knowledge and skill in the treatment of Horizon BCBSNJ members. Horizon BCBSNJ is not responsible for, does not provide, and does not hold itself out as a provider of medical care. The physician remains responsible for the quality and type of health care services provided to a Horizon BCBSNJ member.

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

according to the anatomic site and function of the bone.

The definition of a fracture nonunion has remained controversial. For electrical bone growth stimulators (see Policy No. 10 in the Treatment Section), 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® (also referred to as Exogen 2000®) was initially cleared for marketing by FDA in October 1994 as a treatment of fresh, closed, posteriorly displaced distal radius (Colles') fractures and fresh, closed, or grade-I open tibial diaphysis fractures in skeletally mature individuals when these fractures are orthopedically managed by closed reduction and cast immobilization. In February 2000, the labeled indication was expanded to include the treatment of established nonunions, excluding skull and vertebra. FDA product code: LPQ.

Related Policy

- Electrical Bone Growth Stimulation (Policy #010 in the Treatment Section)

Policy:

1. Low-intensity ultrasound treatment is 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.

Patient comorbidities:

- Diabetes
- Steroid therapy
- Osteoporosis
- History of alcoholism
- History of smoking

Fracture locations:

- Jones fracture
- Fracture of navicular bone in the wrist (also called the scaphoid)
- Fracture of metatarsal
- Fractures associated with extensive soft tissue or vascular damage

2. Low-intensity ultrasound treatment is 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 the Policy Guidelines section for definition of delayed union.)*

3. Low-intensity ultrasound treatment is 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 the Policy Guidelines section for definition of nonunion.)*

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

Policy Guidelines*: (Information to guide in medical necessity determination but should not be utilized as absolute criteria.)*

Fresh (Acute) Fracture

There is no standard definition for a "fresh" fracture. A fracture is most commonly defined as fresh for 7 days after the fracture occurs, (1-3) but there is variability. For example, 1 study defined fresh as less than 5 days after fracture, (4)) while another defined fresh as up to 10 days after fracture. (5) Most fresh closed fractures heal without complications with the use of standard fracture care, ie, closed reduction and cast immobilization.

Delayed Union

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.

Nonunion

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

The definition of nonunion in the U.S. Food and Drug Administration (FDA) labeling suggests that nonunion is considered established when the fracture site shows no visibly progressive signs of healing, without giving any guidance regarding the timeframe of observation. However, it is suggested that a reasonable time period for lack of visible signs of healing is 3 months. The following patient selection criteria are consistent with those proposed for electrical stimulation as a treatment of nonunions (see Policy No. 010 in the Treatment Section):

- *At least 3 months have passed since the date of the fracture, AND*
- *serial radiographs have confirmed that no progressive signs of healing have occurred, AND*
- *the fracture gap is 1 cm or less, AND*
- *the patient can be adequately immobilized and is of an age when he/she is likely to comply with nonweight bearing.*

*[**RATIONALE:***

The policy was initially developed in December 1995. Since that time, the policy has been updated on a regular basis using MEDLINE literature searches. The most recent literature review was conducted through November 25, 2014.

Fresh Fractures

The policy regarding fresh fractures is based in part on a 1995 TEC Assessment that concluded that ultrasound fracture healing met the TEC criteria for the indications labeled by the U.S. Food and Drug Administration (FDA) as a treatment of closed, fresh fractures of the tibial or distal radius (ie, Colles') fractures.(7) Since the TEC Assessment, there have been numerous randomized controlled trials (RCTs) and systematic reviews of clinical trials on the use of ultrasound to improve healing in fresh fractures.

Systematic Reviews

A 2002 meta-analysis conducted by Busse et al(8) supported the use of low-intensity ultrasound as a technique for fractures treated nonoperatively. This systematic review was updated in 2009 and included RCTs of low-intensity pulsed ultrasonography for any type of fracture.(9) Thirteen trials were included; in 5 of them, patients were managed conservatively, and in 8 studies, patients had ultrasound therapy after operative management (distraction osteogenesis in 3 studies, bone graft for nonunion in one, and operative treatment of fresh fractures in 4). Ultrasound therapy significantly accelerated radiographic healing of fractures in all 3 RCTs of conservatively managed fresh fractures that assessed this outcome. (These trials are described in

more detail next.)

The trials of operatively managed (open) fresh fractures outcomes were inconsistent; 4 trials provided low-quality evidence for acceleration of healing by ultrasound 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 quasirandomized. (10,11) The included studies were limited in methodologic quality, with all having some evidence of bias. There was very limited evidence on functional outcomes. Pooling results from 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 operatively treated fractures raised the possibility that pulsed US may be effective in reducing healing time in conservatively managed fractures, but a test for subgroup differences did not confirm a significant difference between the subgroups. The review concluded that while a potential benefit of US for acute fractures could not be ruled out, the currently available evidence was insufficient to support its routine use.

RCTs of Closed Fractures

In a 1997 multicenter RCT by Kristiansen et al, 60 patients with dorsally angulated fractures of the distal radius treated with manipulation and cast were randomly assigned to 10 weeks of daily treatment with a pulsed ultrasound device or an inactive device.(2) All patients started ultrasound within 7 days after having sustained the fracture. Blinded radiographic and clinical examinations showed faster healing in the ultrasound 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 performed a double-blind RCT comparing ultrasound treatment ($n=33$) with a placebo-control device ($n=34$) in closed or grade-I open fractures of the tibial shaft.(1) Treatment was started within 7 days after the fracture and consisted of one 20-minute period each day. Time-to-healing was 86 days in the treatment group versus 114 days in the control group ($p=0.01$), and time to overall (clinical and radiographic) healing was 96 days in the active-treatment group compared to 154 days in the control group ($p<0.001$). Scaphoid fractures were treated with ultrasound in a study done in Germany.(8) Fifteen patients were randomly assigned to treatment and 15 to placebo device groups. Healing was assessed by computed tomography (CT) scans every 2 weeks. Fractures treated with ultrasound healed in 43.2 days versus 62 days in the control group ($p<0.01$). Pooled data from these studies demonstrated a mean reduction in radiographic healing time of 36.9% (95% CI, 25.6% to 46.0%).

Lubbert et al performed a multicenter double-blind RCT of US treatment of fresh (<5 days) clavicle shaft fractures.(4) Patients were taught to use the ultrasound devices for 20 minutes each day for 28 days and to record daily their subjective feeling as to whether the fracture healed or not (the primary outcome measure), pain on visual analog scale (VAS), level of daily

activities once a day expressed as hours of activity (work, household work, sport), and analgesic use. A total of 120 patients (61 active and 59 placebo) started study treatment. Nine patients in the active group and 10 in the placebo group were excluded from analysis because of incomplete follow-up or early withdrawal from the study. The day that the fracture clinically healed according to patient perception was determined in 92 patients (47 active and 45 placebo), and mean duration of time to clinical healing was 26.77 days in the active group versus 27.09 days in the placebo group. Between-group differences in analgesic use and mean VAS were not significant.

RCTs of Open Fractures and Surgically Treated Closed Fractures

For the treatment of open fractures, data are conflicting regarding the efficacy of ultrasonic accelerated fracture healing systems, specifically for patients treated surgically with placement of an intramedullary nail. For example, Emami et al (1999) randomly assigned 32 patients with a fresh tibial fracture that was fixed with an intramedullary rod to undergo additional treatment with an active or inactive US device.(3) US treatment began within 3 days of surgery, and with 1 exception, within 7 days of injury. Time-to-healing was not significantly different in the 2 groups, and the authors concluded that there was no benefit in operatively treated fractures. In contrast, Leung et al (2004) randomly assigned 30 complex tibial fractures (in 28 patients) treated with internal or external fixation to receive or not receive additional treatment with low-intensity US. (12) US treatment was begun when the patient's condition had stabilized, and the open wound was covered with simple closure or skin grafts. The duration of tenderness, time to weight bearing, and time to callus formation were significantly less in those in the US group. Due to the inconsistent results in the 2 small randomized trials, and the negative results of the meta-analysis, lowintensity
US is considered investigational for open fractures.

In 2011 Dijkman et al reported data from a substudy of 51 patients of a larger RCTs that enrolled patients with open or closed tibial shaft fractures that were treated surgically with an intramedullary nail. (13) According to the posting on online site www.ClinicalTrials.gov (NCT00667849), "the study was terminated due to futility", suggesting lack of benefit for this indication.

Section Summary

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

use.

Nonunions

The policy regarding nonunion of fractures is based on data presented to FDA as part of the approval process for Sonic Accelerated Fracture Healing System (SAFHS®) as a treatment of fracture nonunions. The following data were reported and are included in the package insert for the device(14):

- *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 of 74 cases (86%) were healed with use of low-intensity ultrasound. The time-to-healing was 173 days. The healed rate of scaphoid bones was lower, at 33% (2 of 6 cases), which was partially responsible for a significant difference between the healing rates of long bones (92%) versus other bones (67%).*
- *Fracture age also affected healing rates, with fractures over 5 years old having a healing rate of 50% compared to a healing rate of 95% in those present for no more than 1 year.*

A 2007 study used prospectively defined criteria for analysis of all Dutch patients (96 participating clinics) who had been treated with US for established nonunion of the tibia (characterized by a total stop of all fracture repair processes).(15) Included in the analysis were 71 patients who were at least 3 months from the last surgical intervention and did not show any healing improvements in the 3 months before ultrasound treatment (average fracture age, 257 days; range: 180-781). All patients were followed up (average, 2.7 years) by questionnaire, or by phone, if needed. There was an overall healing rate of 73%, at an average 184 days to healing (range, 52-739). No difference in healing rate for open or closed fractures was observed.

Delayed Union

In 2010, Schofer et al. reported an industry-sponsored multicenter randomized double-blinded sham-controlled trial of low-intensity pulsed ultrasound in 101 patients with delayed union of the tibia.(16) 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 the patients had an open fracture. Fifty-one patients were randomized to daily treatment with ultrasound, and 50 were assigned to an inactive sham device (20 minutes daily for 16 weeks). The primary outcome measure was the 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 (24% of sham-treated subjects and 9.8% of active-treated subjects were missing posttreatment values). The mean improvement in BMD was 1.34 (90% CI, 1.14 to 1.57) times greater for ultrasound-treated

subjects compared to sham. Analysis of 'completers' showed a medium effect size (0.53) of the treatment. A mean reduction in bone gap area also favored ultrasound treatment, with a mean change of log gap area of -0.131 mm^2 for the 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 by a 1-sided test. The clinical significance of this difference is unclear. There was a trend (p=0.07) for more subjects receiving low-intensity pulsed ultrasound to be judged to be healed by the participating physicians by the end of the 16-week study period, 65% (33 of 51) of ultrasound versus 46% (23 of 50) sham subjects. While there was not a statistically significant improvement in the rate of healing, the improvements in intermediate outcomes and the 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 examined the effect of 20-minute daily low-intensity pulsed US on tibial stress fracture healing issues such as pain, function, and resumption of professional and personal activities in 26 military recruits.(17) The delay from onset of symptoms to diagnosis was 32 days in the US group and 28 days in the placebo group. Pulsed US did not significantly reduce the healing time for the tibial stress fractures; the time to return to duty was 56 days in each group.

Osteotomy Sites

In 2013, Urita et al. published a small (n=27) quasirandomized study (alternating assignment) of low-intensity pulsed ultrasound after ulnar shortening osteotomy for ulnar impaction syndrome or radial shortening osteotomy for Kienbock disease.(18) Patients in the ultrasound group received once-daily 20-minute ultrasound treatments for at least 12 weeks postoperatively. Blinded evaluation of radiographic healing showed that ultrasound reduced the mean time to cortical union by 27% (57 vs 76 days) and endosteal union by 18% (121 vs 148 days). At the time of endosteal healing (mean, 121 or 148 days), the 2 groups had similar results on the Modified Mayo Wrist Score and no pain at the osteotomy site. Limitations of this study include the lack of a sham control and the long interval between the 16 and 24 week assessments, which may have increased group differences. In addition, clinical outcomes appear to have been assessed only at the time of radiographic healing and did not show any differences at this time point. Additional study is needed to determine with greater certainty the effect of low-intensity pulsed ultrasound 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.(9) In 2011, a small (n=36) nonblinded RCT of low-intensity pulsed ultrasound found no significant differences between the active and control groups in efficacy measures, although the treatment period (fixator gestation period) was decreased by more than 1 month.(19) A 2014 study randomized 21 patients undergoing callus distraction for posttraumatic tibial defects to pulsed US or no treatment (controls).(20) In this

nonblinded study, US shortened healing by 12 d/cm and the total fixator time by 95 days. Double-blind trials with a larger number of subjects are needed to evaluate the health benefits of this procedure.

Ongoing and Unpublished Clinical Trials

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

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

Clinical Input Received From Physician Specialty Societies and Academic Medical Centers

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

2008 Input

In response to requests for input from physician specialty societies and academic medical centers for the 2008 policy update, input was received from 1 physician specialty society while this policy was under review. Physician input obtained through the American Academy of Orthopaedic Surgeons agreed with the positions regarding the criteria for medical necessity and the conditions that are considered investigational (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. Onereviewer 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.

Summary of Evidence

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

Evidence is insufficient to evaluate health outcomes with use of low-intensity ultrasound as a treatment of congenital pseudarthroses, arthrodesis of the appendicular skeleton, or spinal fusions. Use of ultrasound for these conditions is considered investigational. Based on 1 small trial with results showing no benefit to use of ultrasound treatment in the treatment of stress fractures, this is considered investigational.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

The United Kingdom's National Institute for Health and Clinical Excellence (NICE) updated their guidance on low-intensity pulsed ultrasound for the treatment of nonunion and delayed fracture healing in 2013.(21) NICE reached the following conclusions:

> *1.1 The case for adopting the EXOGEN ultrasound bone healing system to treat long-bone fractures with **nonunion** (failure to heal after 9 months) is supported by the clinical evidence, which shows high rates of fracture healing.*

*1.2 The EXOGEN ultrasound bone healing system to treat long-bone fractures with **nonunion** is associated with an estimated cost saving of £1164 per patient compared with current management, through avoiding surgery.*

*1.3 There is some radiological evidence of improved healing when the EXOGEN ultrasound bone healing system is used for long-bone fractures with **delayedhealing** (no radiological evidence of healing after approximately 3 months). There are substantial uncertainties about the rate at which bone healing progresses without adjunctive treatment between 3 and 9 months after fracture, and about whether or not surgery would be necessary. These uncertainties result in a range of cost consequences, some cost-saving and others that are more costly than current management*

The American Academy of Orthopaedic Surgeons (AAOS) published 2009 guidelines on the treatment of distal radius fractures.(22) 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

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

Medicare National Coverage

Effective January 1, 2001, ultrasonic osteogenic stimulators are covered as medically reasonable and necessary for the treatment of nonunion fractures (23) Nonunion fractures of the skull, vertebrae, and those that are tumor-related are excluded from coverage. Ultrasonic osteogenic stimulators may not be used concurrently with other noninvasive osteogenic devices. Ultrasonic osteogenic stimulators for fresh fractures and delayed unions remain noncovered.]

Horizon BCBSNJ Medical Policy Development Process:

This Horizon BCBSNJ Medical Policy (the "Medical Policy") has been developed by Horizon BCBSNJ's Medical Policy Committee (the "Committee") consistent with generally accepted standards of medical practice, and reflects Horizon BCBSNJ's view of the subject health care services, supplies or procedures, and in what circumstances they are deemed to be medically necessary or experimental/ investigational in nature. This Medical Policy also considers whether and to what degree the subject health care services, supplies or procedures are clinically appropriate, in terms of type, frequency, extent, site and duration and if they are considered effective for the illnesses, injuries or diseases discussed. Where relevant, this Medical Policy considers whether the subject health care services, supplies or procedures are being requested primarily for the convenience of the covered person or the health care provider. It may also consider whether the services, supplies or procedures are more costly than an alternative service or sequence of services, supplies or procedures that are at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the relevant illness, injury or disease. In reaching its conclusion regarding what it considers to be the generally accepted standards of medical practice, the Committee reviews and considers the following: all credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, physician and health care provider specialty society

recommendations, the views of physicians and health care providers practicing in relevant clinical areas (including, but not limited to, the prevailing opinion within the appropriate specialty) and any other relevant factor as determined by applicable State and Federal laws and regulations.

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Codes:

(The list of codes is not intended to be all-inclusive and is included below for informational purposes only. Inclusion or exclusion of a procedure, diagnosis, drug or device code(s) does not constitute or imply authorization, certification, approval, offer of coverage or guarantee of payment.)

CPT*

20979

HCPCS

E0760

ICD-9 Diagnosis

ICD-9 Procedure
