The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Preauthorization is required. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

Description

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

Background

The majority of bone fractures heal spontaneously over the course of several months following injury. However, approximately 5-10% of all fractures have delayed healing, resulting in continued morbidity and increased utilization of healthcare 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 non-healing.

The current Protocol does not limit the use of the device to specific fracture sites. According to orthopedic anatomy, the skeleton consists of long bones, short bones, flat bones, and irregular bones. Long bones act as levels to facilitate motion, while short bones function to dissipate concussive forces. Short bones include those comprising the carpus and tarsus. Flat bones, such as the scapula or pelvis, provide a broad surface area for attachment of muscles. Despite their anatomic classification, all bones are composed of a combination of cortical and trabecular (also called cancellous) bone. 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, the U.S. Food and Drug Administration (FDA) labeling defined nonunion as follows: “A nonunion is considered to be established when a minimum of nine months has elapsed since injury and the fracture site shows no visibly progressive signs of healing for minimum of three months.” Others have contended that nine months represents an arbitrary cut-off point that does not reflect the complicated variables that are present in fractures, i.e., degree of soft tissue damage, alignment of the bone fragments, vascularity, and quality of the underlying bone stock. Other proposed definitions of nonunion involve three to six 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 three and nine 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 x-rays. (In contrast, nonunion serial x-rays show no evidence of healing.) Together, delayed union and nonunion are sometimes referred to as “ununited fractures.”

To determine the status of fracture healing, it is important to include both radiographic and clinical criteria. Clinical criteria include the lack of ability to bear weight, fracture pain, and tenderness on palpation.

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

Regulatory Status

The Sonic Accelerated Fracture Healing System, SAFHS® (also referred to as Exogen 2000®) was initially cleared for marketing by the U.S. Food and Drug Administration (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.

Related Protocols

Electrical Bone Growth Stimulation of the Appendicular Skeleton

Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures

Bone Morphogenetic Protein

Policy (Formerly Corporate Medical Guideline)

Low-intensity ultrasound treatment may be considered medically necessary when used as an adjunct to conventional management (i.e., 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.

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

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

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 Guideline

Fresh (Acute) Fractures:

A fracture is most commonly defined as “fresh” for seven days after the fracture occurs. Most freshly closed fractures heal without complications with the use of standard fracture care, i.e., 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 three months from the index injury or the most recent intervention.

Nonunions:

There is not a consensus for the definition of nonunions. One proposed definition is failure of progression of fracture-healing for at least three consecutive months (and at least six months following the fracture) accompanied by clinical symptoms of delayed/nonunion (pain, difficulty weight bearing). (1)

The definition of non-union in the 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 time frame of observation. However, it is suggested that a reasonable time period for lack of visible signs of healing is three months. The following patient selection criteria are consistent with those proposed for electrical stimulation as a treatment of nonunions (see separate Protocol Electrical Bone Growth Stimulation of the Appendicular Skeleton):

- At least three 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 non-weight bearing.

Medicare Advantage

For Medicare Advantage ultrasonic osteogenic stimulators are medically necessary for the treatment of nonunion fractures prior to surgical intervention or after a failed surgical intervention. A nonunion fracture is demonstrated by:

- A minimum of two sets of radiographs, obtained prior to starting treatment with the osteogenic stimulator, separated by a minimum of 90 days. Each radiograph set must include multiple views of the fracture site
accompanied with a written interpretation by a physician stating that there has been no clinically significant
evidence of fracture healing between the two sets of radiographs.

It is **not medically necessary** to use ultrasonic osteogenic stimulators concurrently with other non-invasive
osteogenic devices.

Ultrasonic osteogenic stimulators for fresh fractures and delayed unions, and fractures of the skull, vertebrae or
related to a tumor are **not medically necessary**.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are
considered investigational. *For explanation of experimental and investigational, please refer to the Technology
Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to
conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced
procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to
products that are not available in your geographic area.**

**References**

We are not responsible for the continuing viability of web site addresses that may be listed in any references
below.

1. Bhandari M, Fong K, Sprague S et al. Variability in the definition and perceived causes of delayed unions and

2. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Ultrasound accelerated fracture
healing. TEC Assessments 1995; Volume 10, Tab 14.


6. Kristiansen TK, Ryaby JP, McCabe J et al. Accelerated healing of distal radial fractures with the use of
specific, low-intensity ultrasound. A multicenter, prospective, randomized, double-blind, placebo-controlled


8. Lubbert PH, van der Rijt RH, Hoornhte LE et al. Low-intensity pulsed ultrasound (LIPUS) in fresh clavicle


