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
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. According to the FDA labeling, a nonunion is considered to be established when the fracture site shows no visibly progressive signs of healing.

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

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, excluding the skull and vertebra.

Low-intensity ultrasound treatment may be considered medically necessary as a treatment of fracture nonunions of bones 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, or stress fractures.

Policy Guideline

Fresh 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 x-rays, together with a 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.

Nonunions:
The FDA labeling simply 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 suggested, 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.


