

Medical Coverage Policy



**Blue Cross
Blue Shield**
of Rhode Island

Ultrasound Accelerated Fracture Healing Therapy

Device/Equipment Drug Medical Surgery Test Other

Effective Date:	10/4/2011	Policy Last Updated:	05/7/2013
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Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.

Prospective review is not required.

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.

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.

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.

Fresh (Acute) Fracture

Most fresh 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.

Nonunion

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 timeframe of observation. However, it is suggested that a reasonable time period for lack of visible signs of healing is 3 months.

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 (RCTs), 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, i.e., 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 may be 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, including, but not limited to, congenital pseudarthroses, arthrodesis and failed arthrodeses of the appendicular skeleton, spinal fusions, or stress fractures or any treatment to sesamoid bones. Use of ultrasound for these conditions is considered not medically necessary as there is no proven efficacy.

Medical Criteria:

1. Fresh Fractures

A fresh closed fracture is defined as one that is less than 14 days old with closed skin over the broken bone. 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 who meet **one** of the following criteria for **either patient comorbidities or fracture location:**

Any 1 or more of the following patient comorbidities:

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

OR

Any 1 or more of the following 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
- Fracture of the tibia

2. Delayed Union

A delayed union is defined as one that has not healed in a period of time that would normally be considered adequate. 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. Although slower than expected, the healing process is continuing and will eventually occur. Low-intensity ultrasound treatment is **medically necessary** in the treatment of delayed unions, excluding the skull and vertebra.

3. Nonunion Fractures

A nonunion fracture is defined as one that after standard treatment has not shown visibly progressive signs of healing as determined by X-rays, in a normal timeframe (4 to 12 weeks).

Low-intensity ultrasound treatment may be considered **medically necessary** when used as an adjunct to standard management (closed reduction and cast immobilization) for the treatment in skeletally mature individuals with nonunion fractures meeting **ALL** of the following criteria.

- a minimum of three months have passed since date of 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 where he/she is likely to comply with non-weight bearing.

Policy:

Prior authorization is required for BlueCHiP for Medicare and recommended for all other products.

Low-intensity ultrasound treatment may be considered **medically necessary when the medical criteria is met**. Other applications of low-intensity ultrasound treatment are **considered not medically necessary** as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective.

Coverage:

Benefits may vary between groups/contracts. Please refer to the appropriate member certificate/subscriber agreement/statement of coverage for applicable durable medical equipment (DME)/surgery benefits/coverage.

Coding:

The following code is covered and separately reimbursed under the surgery benefit:
20979

The following code is covered under the durable medical equipment benefit:
E0760

Also Known As:

Ultrasound therapy for fractures

Related Topics:

Electrical Bone Growth Stimulation

Published:

Policy Update, July 2013
Provider Update, Apr 2012
Provider Update, Dec 2011
Provider Update, Jun 2011
Provider Update, Dec2009
Provider Update, Oct 2008
Policy Update, Dec 2007
Policy Update, Feb 2007
Policy Update, Dec 2006
Policy Update, Jan 2006
Policy Update, Feb 2005
Policy Update, Jul 2002
Policy Update, Mar 2000

Policy Update, Mar 1998
Policy Update, Nov 1997

References:

¹CMS Transmittal: CR4085. <http://www.cms.hhs.gov/Transmittals/downloads/R816CP.pdf>.

Bhandari M, Fong K, Sprague S et al. Variability in the definition and perceived causes of delayed unions and nonunions: a cross-sectional, multinational survey of orthopaedic surgeons. *J Bone Joint Surg Am* 2012; 94(15):e1091-6.

National Institute for Health and Clinical Excellence. Low-intensity pulsed ultrasound to promote fracture healing. 2010. Available online at: <http://www.nice.org.uk/nicemedia/live/12408/52076/52076.pdf>

Centers for Medicare and Medicaid Services. National Coverage Decision for Osteogenic Stimulators (150.2) 2005. Available online at: http://www.cms.hhs.gov/mcd/viewnacd.asp?ncd_id=150.2&ncd_version=2&basket=ncd%3A150%2E2%3A2%3AOsteogenic+Stimulators

Busse JW, Bhandari M, Kulkarni AV, Tunks E. *The effect of low-intensity pulsed ultrasound therapy on time to fracture healing: a meta-analysis*. *Canadian Medical Association Journal*;2002;166:437-41.
Heckman JD, Ryabyt JP, McCabe J, Frey JJ, Kilcoyne RF. *Acceleration of Tibial Fracture-Healing by Non-Invasive, Low-Intensity Pulsed Ultrasound*. *The Journal of Bone and Joint Surgery*; 1994;76:26-34.

History:

Annual Update - March 2013

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