Medical Coverage Policy

Ultrasound Accelerated Fracture Healing Therapy--PREAUTH

- Device/Equipment
- Drug
- Medical
- Surgery
- Test
- Other

Effective Date: 10/4/2011  
Policy Last Updated: 2/21/2012

Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.

Prospective review is not required.

Description:

The ultrasound fracture healing device is a non-invasive device that uses low-intensity, pulsed ultrasound therapy to stimulate fracture healing. Treatment is delivered directly to the fracture using a transducer applied to the skin surface with a conductive coupling gel. The device is portable and can be self-administered in daily 20-minute treatments until the fracture is healed. This device is intended for use with cast immobilization.

Cleared for marketing by the United States Food and Drug Administration (FDA) in October 1994, the Sonic Accelerated Fracture Healing System (SAFHS) was initially used as a treatment for fresh, closed, posteriorly displaced distal radius (Colles') fractures and fresh, closed, or grade I open tibial diaphysis fractures in skeletally mature individuals when fractures could be orthopaedically managed by closed reduction and cast immobilization. In February 2000, the indication was expanded to include treatment of all established nonunions except those of the skull and vertebra. A nonunion is defined by the FDA as a fracture which shows no visibly progressive signs of healing.

Definitions:

Fresh Fractures

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 3 months.

**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

   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 **not medically necessary**, including, but not limited to, treatment of congenital pseudarthroses, open fractures, or stress fractures due to lack of peer-reviewed medical literature that supports use.
2. **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.

3. **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.

**Policy:**

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

Low-intensity ultrasound treatment may be considered **medically necessary** as a treatment of fracture nonunions of bones excluding the skull and vertebra.

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 **not medically necessary**, including, but not limited to, treatment of congenital pseudarthroses, open fractures, or stress fractures.
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 Ostogenesis stimulator, low-intensity ultrasound, non-invasive

Also Known As:

Ultrasound therapy for fractures

Related Topics:

Not applicable

Published:

Policy Update, Nov 1997
Policy Update, Mar 1998
Policy Update, Mar 2000
Policy Update, Jul 2002
Policy Update, Feb 2005
Policy Update, Jan 2006
Policy Update, Dec 2006
Policy Update, Feb 2007
Policy Update, Dec 2007
Provider Update, Oct 2008
Provider Update, Dec 2009
Provider Update, Jun 2011
Provider Update, Dec 2011
Provider Update, Apr 2012

References:

1 CMS Transmittal: CR4085.
American Academy of Orthopedic Surgeons (AAOS). Nonunions: 


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