



ULTRASOUND ACCELERATED FRACTURE HEALING DEVICE
DME101.030

COVERAGE:

Low-intensity ultrasound treatment MAY BE ELIGIBLE FOR COVERAGE as it is 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.

Low-intensity ultrasound treatment MAY BE ELIGIBLE FOR COVERAGE as it is considered medically necessary as a treatment of fracture nonunions of bones excluding the skull and vertebra.

Other applications of low-intensity ultrasound treatment are investigational, including but not limited to treatment of delayed unions (defined as a decelerating healing process as determined by serial x-rays) or congenital pseudarthroses.

DESCRIPTION:

Low-intensity pulsed ultrasound has been principally investigated as a technique to accelerate healing of fresh fractures, but more recently as a treatment of fracture nonunions.

The FDA labeling suggest that a nonunion is considered to be 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.

The most appropriate candidates for ultrasound treatment may be those at high risk for delayed fracture healing or nonunion. These risk factors may include both of the following:

Patient co-morbidities:

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

Fracture locations:

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

Ultrasound can be delivered noninvasively 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 actions at the cellular level is not precisely known but is thought to be related to a mechanical effect caused by cell deformation. The ultimate effect on fracture healing may be mediated by enhanced vascularity at the fracture site or enhanced chondrocyte maturation.

The Sonic Accelerated Fracture Healing System (SAFHS® Exogen, Inc.) was cleared for marketing by the FDA in October 1994 as a treatment of fresh, closed, posteriorly displaced distal radius (Colles') fractures and fresh, closed, or grade 1 open tibial diaphysis fractures in skeletally mature individuals when 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 established when the fracture site shows no visibly progressive signs of healing.

RATIONALE:

Fresh Fractures:

The coverage criteria regarding fresh fractures is based in part on a 1995 TEC assessment that concluded that ultrasound fracture healing met the TEC criteria for the FDA-labeled indications as a treatment of closed, fresh fractures of the tibia or distal radius (i.e., Colles'). 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 expansion of the policy to include 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.

Nonunions:

The coverage criteria regarding fracture nonunions is based on data presented to the FDA as part of the approval process for SAFHS as a treatment of fracture nonunions. The following data were reported and are included in the package insert for the device:

- 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 any intervention.
- A total of 64 of 74 cases (86%) were healed with use of low-intensity ultrasound. Healing time was 173 days. The healed rate of scaphoid bones was lower 33% (2 of 6 cases), which was partially responsible for a significant difference between the healing rates of long bones (92%) vs. 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 a year.

DISCLAIMER:

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, takes precedence over Medical Policy and must be considered first in determining coverage. The member's contract benefits in effect on the date that services are rendered must be used. Any benefits are subject to the payment of premiums for the date on which services are rendered. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

HMO Blue Texas physicians who are contracted/affiliated with a capitated IPA/medical group must contact the IPA/medical group for information regarding HMO claims/reimbursement information and other general policies and procedures.

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