



Medical Policy Reference Manual

Medical Policy

1.01.006 Ultrasound Accelerated Fracture Healing Device

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▼ Description

Ultrasound accelerated fracture healing involves a non-invasive device that uses a low-intensity pulsed ultrasound (LIPUS) signal applied to the skin surface overlying the fracture site. The ultrasound signal is transmitted to the skin via a conductive coupling gel, which coats the skin surface. The intensity of the applied ultrasound energy is comparable to that used in conventional fetal monitoring. Ultrasound treatment can be self-administered with one daily 20-minute treatment until there is evidence of clinical fracture repair.

An example of such a device is the Sonic Accelerated Fracture Healing System SAFHS® (also referred to as Exogen 2000®). It 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 vertebrae. According to the FDA labeling, a nonunion is considered to be established when the fracture site shows no visibly progressive signs of healing.

* **NOTE:** skeletally mature - when bone growth is complete; the growth plates (epiphyseal plates) have closed.

NOTE: Electrical Bone Growth Stimulation is not addressed in this policy. See *Electrical Bone Growth Stimulation, Policy 7.01.007*.

▼ Policy

Non-invasive low-intensity ultrasound treatment is considered **medically necessary** when used as an adjunct to conventional management (closed reduction and cast immobilization) for the treatment of fresh, closed fractures in skeletally mature individuals.

Non-invasive low-intensity ultrasound treatment is considered **medically necessary** as a treatment of delayed union of bones, excluding the skull and vertebra. 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.

Non-invasive low-intensity ultrasound treatment is considered **medically necessary** as a treatment of fracture nonunion of bones, excluding the skull and vertebra. A nonunion fracture is defined as a situation where an unhealed fracture has shown no radiological evidence of progress toward healing in the past three months, **and** where the fracture gap is less than or equal to 1.0 cm.

Other applications of non-invasive low-intensity ultrasound treatment including, but not limited to, congenital pseudarthroses, open fractures, or stress fractures, are considered **experimental / investigational**, as this use does not meet TEC criteria # 2 - 5.

▼ Policy Guidelines

Rationale:

A review of available peer-reviewed literature does not support the use of an ultrasound accelerated healing device for fracture healing other than those medically necessary indications outlined in the Policy section of this document.

Update 2008:

A search of the peer-reviewed literature was performed for the period of May 2006 through March 2008. The policy statements were revised to include treatment, where indicated, of any fresh fracture in skeletally mature individuals as an adjunct to conventional treatment and for the treatment of a nonunion fracture, excluding the skull and vertebra, as defined in the policy.

Update 2010:

A search of the peer-reviewed literature was performed from April 2008 through April 2010. The experimental / investigational policy statement has been updated to reflect the current peer-reviewed literature. Findings in the recent literature do not change the conclusions regarding the medically necessary indications for the use of ultrasound accelerated fracture healing devices.

Update 2012:

A search of the peer-reviewed literature was performed from April 2010 through April 2012. The policy statements were revised to include treatment of delayed union of bones as a medically necessary indication for non-invasive low intensity ultrasound.

Update 2014:

A search of the peer-reviewed literature was performed from May 2012 through May 2014. Findings in the recent literature do not change the conclusions regarding medically necessary indications for the use of ultrasound accelerated fracture healing devices.

▼ Benefit Applications

NOTE: For FEP, check the member's contract for benefits.

▼ Cross References to Related Policies and Procedures

Electrical Bone Growth Stimulation, Policy 7.01.007.

▼ References

The following were among the resources reviewed and considered in developing this policy. By reviewing and considering the resources, CareFirst does not in any way endorse the contents thereof nor assume any liability or responsibility in connection therewith. The opinions and conclusions of the authors of these resources are their own, and may or may not be in agreement with those of CareFirst.

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