



Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Osteogenic (Bone) Stimulators

- Non-invasive Electrical Stimulators
- Implantable Electric Stimulators
- Ultrasonic Stimulators

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Osteogenic Stimulators (150.2)
Local Coverage Determinations (LCD)	Osteogenesis Stimulators (L33796)
Local Coverage Article	Osteogenesis Stimulators (A52513)

For Non-Medicare Members

Electric Bone Growth Stimulators (Non-invasive and Implantable)

Kaiser Permanente has elected to use the Bone Growth Stimulators, Electrical and Electromagnetic (A-0565) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

Ultrasonic Bone Growth Stimulators

Kaiser Permanente has elected to use the Bone Growth Stimulators, Ultrasonic (KP-0414) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***MCG manuals are proprietary and cannot be published and/or distributed.** However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting these services, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist (Orthopedics/podiatry)
- Copies of last 12 months of x-rays of involved area

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Electrical stimulation has been used as treatment for nonunion of fractures since the early 1950's with a reported success rate of 80-85%. New devices have made the use of this method of treatment more attractive. Bone Stimulators are covered in Kaiser Permanente plans that include coverage for durable medical equipment. The criteria for coverage had previously been part of the Durable Medical Equipment Formulary. The average contracted cost of the device is \$3,000. Because of the renewed attention on this mode of treatment by Kaiser

Permanente orthopedists, the referral management staff requested that clearer criteria be developed for reviewing coverage requests (1/97).

Fracture healing is a highly complex biological process. The healing process is delayed in approximately 10% of the 6 million fractures that occur annually in the United States. A portion of these delayed unions do not heal by 9 months after fracture and are categorized as non-unions (Hadjiargyrou, 1998). There are two types of bone growth stimulators: electric and ultrasonic.

Electrical stimulation has been found to offer a reasonable means of treatment for nonunion that have failed to respond to previous bone grafting over an extended period of time. The effective use of electrical stimulation devices requires an understanding of the various principles and concepts employed by the four types of stimulators currently available. While the exact mechanism of electrically induced osteogenesis is uncertain, current theories indicate that several factors probably are involved, and more than one mechanism may be responsible.

Ultrasound, a form of mechanical energy that is transmitted through and into biological tissues, has a variety of diagnostic and therapeutic clinical applications. Research on the use of ultrasound to accelerate the healing of fractures has been done largely using animal models. For example, a study with rabbits found that bones exposed to ultrasound healed in about half the time as untreated bones. Data from animal models suggest that ultrasound may accelerate healing by increasing the blood flow at the fracture site (Rubin, 2001).

Exogen (Smith and Nephew) manufactures a low-intensity ultrasound device for treating fractures, Sonic Accelerated Fracture Healing System (SAFHS). According to the manufacture, the SAFHS system is a portable, battery-operated device that produces ultrasonic waves of 30 milliwatts per cm² (comparable to ultrasound intensity levels used on sonograms for fetal monitoring). Patients apply the ultrasound waves directly to the fracture site.

The FDA approved the use of low-intensity ultrasound for fresh fractures in 1994 based on two randomized controlled trials and Exogen's registry data. In 2000, the FDA extended the use of ultrasound to treating established non-unions.

Medical Technology Assessment Committee (MTAC)

Ultrasonic Bone Stimulator

10/10/2001: MTAC REVIEW

Evidence Conclusion: *Fresh fractures:* Two of the RCTs (Heckman, Kristiansen) were conducted by some of the same investigators. Both found a significantly shorter time to healing for fractures in patients treated with an ultrasonic bone stimulator healed than those treated with a placebo device. Both studies had similar methodological flaws, the most serious of which was that neither study had a primary intention to treat analysis and about 30% of fractures were not included in the analysis. Both studies include a brief description of a secondary intention-to-treat analysis which found statistically significant differences between the ultrasonic bone stimulation and placebo groups; no point estimates, tables or figures were included to support these analyses. Both studies were funded by Exogen and included co-authored by an Exogen employee which could bias the study design and analysis. A third RCT was conducted by investigators without financial ties to Exogen. That study did not find a significant difference in time to radiographic healing between patients receiving ultrasonic bone stimulation versus placebo. This was a small study which may not have had sufficient statistical power to detect a difference if one existed. The threats to validity in the RCTs limit the ability to draw conclusions about the effect of ultrasonic bone stimulation on health outcomes among patients with fresh fractures. *Non-union fractures:* There were no published articles to evaluate the efficacy of ultrasound treatment to heal non-union fractures.

Articles: The search yielded 35 articles. Articles that were opinion pieces, editorials, reviews or on technical aspects of the treatment of fractures with ultrasound were not reviewed. There were 3 RCTs on the use of ultrasound with fresh fractures. Evidence tables were created for these 3 RCTs. There were no published articles on non-union fractures. There was one published abstract by Gebauer, but insufficient information was given in the abstract to evaluate it as evidence. *Citations for the RCTs reviewed:* Emami A, Petren-Mallmin M, Larsson S. No effect of low-intensity ultrasound on healing time of intramedullary fixed tibial fractures. *J Orthop Trauma* 1999; 13: 252-7. See [Evidence Table](#). Kristiansen TK, Ryabi JP, McCabe J, Frey JJ, Roe LR. Accelerated healing of distal radial fractures with the use of specific, low-intensity ultrasound. *J Bone Joint Surg* 1997; 79-A: 961-73. See [Evidence Table](#). Heckman JD, Ryabi JP, McCabe J, Frey JJ, Kilcoyne RF. Acceleration of tibial fracture-healing by non-invasive low-intensity pulsed ultrasound. *J Bone Joint Surg* 1994; 76-A: 26-34. See [Evidence Table](#)

The use of Ultrasonic Bone Stimulator for treatment of fresh and non-union fractures has been approved by the FDA and therefore meets *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Electrical Bone Growth Stimulator:

Medicare: Considered Medically Necessary when criteria in the applicable policy statements listed above are met

CPT® or HCPC Codes	Description
20974	Electrical stimulation to aid bone healing; noninvasive (nonoperative)
20975	Electrical stimulation to aid bone healing; invasive (operative)
E0747	Osteogenesis stimulator, electrical, noninvasive, other than spinal applications
E0748	Osteogenesis stimulator, electrical, noninvasive, spinal applications
E0749	Osteogenesis stimulator, electrical, surgically implanted

Non-Medicare: Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
20974	Electrical stimulation to aid bone healing; noninvasive (nonoperative)
20975	Electrical stimulation to aid bone healing; invasive (operative)
E0748	Osteogenesis stimulator, electrical, noninvasive, spinal applications
E0749	Osteogenesis stimulator, electrical, surgically implanted

Non-Medicare: Considered not medical necessary

CPT® or HCPC Codes	Description
E0747	Osteogenesis stimulator, electrical, noninvasive, other than spinal applications

Ultrasonic Bone Growth Stimulator:

Medicare: Considered Medically Necessary when criteria in the applicable policy statements listed above are met

Non-Medicare: Considered Medically Necessary when criteria in the applicable policy statements listed above are met

CPT® or HCPC Codes	Description
20979	Low intensity ultrasound stimulation to aid bone healing, noninvasive (nonoperative)
E0760	Osteogenesis stimulator, low intensity ultrasound, noninvasive

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

**To verify authorization requirements for a specific code by plan type, please use the [Pre-authorization Code Check](#).

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Date	Dates Reviewed	Date Last
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Created		Revised
09/25/1997	06/01/2010 ^{MDCRPC} , 04/05/2011 ^{MDCRPC} , 02/07/2012 ^{MDCRPC} , 12/04/2012 ^{MDCRPC} , 10/01/2013 ^{MPC} , 08/05/2014 ^{MPC} , 06/02/2015 ^{MPC} , 05/03/2016 ^{MPC} , 03/07/2017 ^{MPC} , 01/09/2018 ^{MPC} , 12/04/2018 ^{MPC} , 12/03/2019 ^{MPC} , 12/01/2020 ^{MPC} , 12/07/2021 ^{MPC} , 12/06/2022 ^{MPC}	11/06/2023

Revision History	Description
06/11/2015	CPT codes added
01/08/2019	MPC adopted hybrid criteria for Ultrasonic Bone Growth Stimulators (KP-0414)
04/03/2023	Updated Medicare links
11/6/2023	Updated codes section and Medicare links