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Review Criteria

Georgia Region

DEPARTMENT:	Quality Resource Management	CRITERIA NUMBER:	No. 05-01
SECTION:	Utilization Management	EFFECTIVE DATE:	7/27/2023
TITLE:	Ultrasound and Electric Osteogenesis Stimulators, Noninvasive	LAST REVIEW DATE:	N/A
		NEXT REVIEW DATE:	2/2024
CRITERIA TYPE:	New	PAGE NUMBER:	Page **1** of **5**
APPROVAL BODY/ COMMITTEE:	Physician Program Director - QRM & Chief of Podiatry		

1.0 DESCRIPTION

1.1 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 inclusion of all bones regardless of the anatomic site is based on this histologic similarity of all bones; it is not anticipated that the effectiveness of ultrasound-accelerated healing would vary according to the anatomic site and function of the bone. Low-intensity pulsed ultrasound (LIPUS) can be delivered non-invasively using a transducer applied to the skin surface over the fracture site through a window cut into a cast or directly at the fracture line with a gelled head unit connected to a generator. It is important that the ultrasound is directly over the fracture or gap; this treatment location is determined by x-ray and the skin is marked. The portable, battery-powered treatment system is administered by the patient or his caregiver for 20 minutes daily for the period needed. Compliance with the protocol for use can be checked when the unit is turned in unless the battery has run low enough to erase the data. The low-intensity pulsed ultrasound level is comparable to diagnostic ultrasound used in sonogram (fetal monitoring) procedures and is 1 – 5% the intensity used for conventional therapeutic ultrasound. Neither physician nor the patient can select or change the signal specifications of the device. The Sonic Accelerated Fracture Healing System, SAFHS® (the device is also known as Exogen e.g., 2000, 3000, 4000) 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 nonunion, excluding skull and vertebra. The FDA labeling suggests that a nonunion is 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 for a lack of visible signs of healing is 3 months.

2.0 DIAGNOSIS/CONDITION

N/A

3.0 CPT/HCPCS CODES AND DESCRIPTIONS

N/A

4.0 INDICATIONS

4.1 Criteria for approval: Low-intensity **ultrasonic or electric** stimulator treatment meets the definition of medical necessity for:

4.1.1 The treatment of fresh closed fractures in skeletally mature individuals when used as an adjunct to conventional management (i.e., closed reduction and cast immobilization). Candidates for low-intensity ultrasound treatment are those at high risk for delayed fracture healing or nonunion.

4.1.1.1 These risk factors may include either fracture locations or patient comorbidities that include the following:

Patient comorbidities:

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

Fracture locations:

- Jones fracture [fracture of the diaphysis of the fifth metatarsal of the foot]
- Fracture of the navicular bone in the wrist (also called the scaphoid)
- Fracture of metatarsal
- Fractures associated with extensive soft tissue or vascular damage

OR

4.1.2 For treatment of delayed union of bones, including delayed union of previously surgically treated fractures, excluding the skull and vertebra. (Delayed union is determined by serial radiographs, along with a lack of clinical and radiologic evidence of union, bony continuity, or bone reaction at the fracture site for no less than 3 months from the index injury or the most recent intervention).

OR

4.1.3 For treatment of fracture nonunions of bones, including nonunion of previously surgically treated fractures, excluding the skull and vertebra. The following selection criteria are for the treatment of nonunion fractures (FDA):

- At least 3 months have passed since the date of the 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 member can be adequately immobilized and is of an age when he/she is likely to comply with non-weight bearing.

5.0 CONTRAINDICATIONS

5.1 Other applications of low-intensity ultrasound treatment are considered experimental or investigational including application for the treatment of the following as there is insufficient clinical evidence to determine health outcomes (this is not an all-inclusive list) and **will not be approved**:

- Congenital pseudarthroses; **OR**
- Open fractures; OR
- Fresh surgically-treated closed fractures; OR
- Stress fractures; **OR**
- Arthrodesis; **OR**
- Failed arthrodesis.

6.0 DEFINITIONS

6.1 **Colles fracture**: a fracture of the distal radius with displacement and/or angulation of the distal fragment dorsally.

6.2 **Delayed union**: a decelerating healing process as determined by serial radiographs, together with a lack of clinical and radiologic evidence of union, bony continuity, or bone reaction at the fracture site for no less than 3 months from the index injury or the most recent intervention. Diaphyseal: pertaining to or affecting the shaft of a long bone (diaphysis).

6.3 **Fresh (acute) fracture**: most commonly defined as “fresh” for 7 days after the fracture occurs. Most fresh closed fractures heal without complications with the use of standard fracture care (i.e., closed reduction and cast immobilization). Index injury: initial injury.

6.4 **Nonunion fractures**: There is not a consensus for the definition of nonunions. One proposed definition is failure of progression of fracture-healing for at least 3 consecutive months (and at least 6 months following the fracture) accompanied by clinical symptoms of delayed/nonunion (pain, difficulty weight bearing). The definition of nonunion in 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.

7.0 **REFERENCES**

7.1 American Academy of Orthopaedic Surgeons. The treatment of distal radius fractures. 2009.

7.2 Blue Cross Blue Shield Association Evidence Positioning System® 1.01.05 Low Intensity Pulsed Ultrasound Fracture Healing Device, 04/22.

7.3 Biglari B, Yildirim TM, Swing T et al. Failed treatment of long bone nonunions with low intensity pulsed ultrasound. Archives of Orthopaedic and Trauma Surgery 2016; 136(8): 1121-1134.

7.4 Busse JW, Bhandari M, Einhorn TA etal. Re-evaluation of low intensity pulsed ultrasound in treatment of tibial fractures (TRUST): randomized clinical trial. BMJ. 2016 Oct 25; 355:i5351.

7.5 Gopalan A, Panneerselvam E, Doss GT, et al. Evaluation of efficacy of low intensity pulsed ultrasound in facilitating mandibular fracture healing-a blinded randomized controlled clinical trial. J Oral Maxillofac Surg. 2020 Jun;78(6): 997.e1-997.e7. [Abstract].

7.6 Griffith XL, Costello L, Costa ML. The role of low intensity pulsed ultrasound therapy in the management of acute fractures: A systematic review. J Trauma. 2008; 65:1446-1452.

7.7 Harrison A, Lin S, Pounder N et al. Mode & mechanism of low intensity pulsed ultrasound (LIPUS) in fracture repair. Ultrasonics 2016; 70: 45-52.

7.8 Leighton R, Watson JT, Giannoudis P et al. Healing of fracture nonunions treated with low-intensity pulsed ultrasound (LIPUS): A systematic review and meta-analysis. Injury 2017; 48(7):1339-1347

7.9 Lou S, Lv H, Li Z et al. The effects of low-intensity pulsed ultrasound on fresh fracture: A meta-analysis. Medicine 2017. Sep; 96(39): e8181.

7.10 National Guideline Clearinghouse. Lower extremity injury medical treatment guidelines. Colorado Division of Workers' Compensation. Lower extremity injury medical treatment guidelines. Denver (CO): Colorado Division of Workers' Compensation; 2009 Jun 24.

7.11 National Institute for Health and Care Excellence. NICE medical technology guidance 12: EXOGEN ultrasound bone healing system for long bone fractures with non-union or delayed healing. 2013.

7.12 Parvizi J, Vegari D. Pulsed low-intensity ultrasound for fracture healing. Foot Ankle Clin N Am. 2005;10: 595-608.

7.13 Poolman RW, Agoritsas T, Siemieniuk RA et al. Low intensity pulsed ultrasound (LIPUS) for bone healing: a clinical practice guideline. BMJ. 2017 Feb 21;356:j576.

7.14 Schandelmaier S, Kaushal A, Lytvyn L et al. Low intensity pulsed ultrasound for bone healing:systematic review of randomized controlled trials. BMJ. 2017 Feb 22;356:j656.

7.15 Song MH, Kim TJ, Kang SH, et al. Low-intensity pulsed ultrasound enhances callus consolidation in distraction osteogenesis of the tibia by the technique of lengthening over the nail procedure. BMC Musculoskelet Disord. Mar 14 2019; 20(1): 108.

7.16 Zura R, Della Rocca GJ, Mehta S. Treatment of chronic (>1 year) fracture nonunion: heal rate in a cohort of 767 patients treated with low-intensity pulsed ultrasound (LIPUS). Injury 2015; 46(10): 2036-2041.

7.17 17. Zura R, Mehta S, Della Rocca GJ et al. A cohort study of 4,190 patients treated with low-intensity pulsed ultrasound (LIPUS): findings in the elderly versus all patients. BMC Musculoskeletal Disorders 2015. Mar; 16: 45.