

# **Bone Growth (Electronic and Ultrasonic) Stimulators**

State(s): ⊠ Idaho	☑ Montana ☑ Oregon ☑ Washington ☐ Other:	LOB(s):  ⊠ Commercial ⊠ Medicare ⊠ Medicaid □ PSA

### **Enterprise Policy**

Clinical Guidelines are written when necessary to provide guidance to providers and members in order to outline and clarify coverage criteria in accordance with the terms of the Member's policy. This Clinical Guideline only applies to PacificSource Health Plans, PacificSource Community Health Plans, and PacificSource Community Solutions in Idaho, Montana, Oregon, and Washington. Because of the changing nature of medicine, this list is subject to revision and update without notice. This document is designed for informational purposes only and is not an authorization or contract. Coverage determination are made on a case-by-case basis and subject to the terms, conditions, limitations, and exclusions of the Member's policy. Member policies differ in benefits and to the extent a conflict exists between the Clinical Guideline and the Member's policy, the Member's policy language shall control. Clinical Guidelines do not constitute medical advice nor guarantee coverage.

# **Background**

Electronic or ultrasound bone growth stimulators are used to hasten the repair of bone fractures, or to facilitate the healing process induced by bone grafting, by promoting the body's natural bone repair process. There are four types of bone growth stimulators, three of which are electronic (EBGS), and one is ultrasonic (UBGS):

- 1. Invasive electronic bone growth stimulators are used as an adjunct to non-cervical spinal fusion, (and are implanted at the time of surgery), or for non-union fractures. The invasive device uses direct current, and the power source is removed in a second surgical procedure when the stimulation is completed.
- 2. Non-invasive electronic bone growth stimulators are externally placed, and use either pulsed electromagnetic fields (PEMF), direct current capacitive coupling, or combined electromagnetic field (CMF) technology.
- **3. Semi-invasive electronic bone growth stimulators** use direct current electrical stimulation via a percutaneous cathode and anode placed in contact with the skin.
- **4. Ultrasonic bone growth stimulators, using low intensity pulsed ultrasound**, are used to accelerate healing of fractures while receiving conventional treatment.

All requested Bone Growth Stimulator Devices must be FDA approved for the area of intended use.

#### Criteria

#### Commercial

### Prior authorization is required.

I. Ultrasonic bone growth stimulators must meet "Clinical Indications" listed in MCG™ ACG: A 0414 Bone Growth Stimulators. Ultrasonic.

#### II. Electronic Bone Growth Stimulators must meet one of the following criteria:

#### A. Non-invasive electrical bone stimulator

PacificSource may consider non-invasive electrical bone stimulator medically necessary as a treatment of patients with failed spinal fusion. Failed spinal fusion is defined as a spinal fusion, which has not healed at a minimum of 6 months after the original surgery, as evidenced by serial x-rays at least 90 days apart.

### B. Invasive or non-invasive bone growth stimulators

PacificSource may consider invasive or non-invasive EBGS medically necessary when **ALL** of the following criteria are met:

- 1. Adjunct to cervical or lumbar fusion; and
- 2. ONE or more of the following risk factors for failed fusion are present:
  - **a.** One or more previously failed lumbar or cervical spinal fusion(s);
  - **b.** Grade III or worse spondylolisthesis;
  - **c.** Fusion to be performed at more than one level;
  - d. Current smoker;
  - e. Diabetes;
  - f. Renal disease; and/or
  - g. Poor nutrition, particularly protein deficiency.

#### C. Invasive, non-invasive, or semi-invasive EBGS

PacificSource may consider invasive, non-invasive, or semi-invasive EBGS medically necessary as treatment of fracture non-unions or congenital pseudoarthroses in the appendicular skeleton. (The appendicular skeleton includes the bones of the shoulder girdle, upper extremities, pelvis, and lower extremities including the metatarsal bones.)

The diagnosis of fracture non-union must meet **ALL** of the following criteria:

- 1. At least 3 months have passed since the date of fracture:
- 2. Serial radiographs at least 90 days apart have confirmed that no progressive signs of healing have occurred:
- 3. The fracture gap is one centimeter or less; AND
- **4.** The patient can be adequately immobilized and is likely to comply with non-weight bearing.

### **Medicaid**

PacificSource Community Solutions follows Oregon Health Plan's Oregon Administrative Rules (OAR) 410-122-0510 criteria for Ultrasonic Bone Growth Stimulators (E0760) and Electronic Bone Growth Stimulators (E0747- E0748).

### **Medicare**

PacificSource Medicare follows CMS Local Coverage Determination LCD L33796 for coverage of Osteogenesis Stimulators.

#### **Exclusions for all LOBs:**

PacificSource considers the use of an ultrasonic osteogenesis stimulator for the treatment of a fresh fracture or delayed union to be not medically necessary.

PacificSource considers the use of an ultrasonic osteogenesis stimulator as not medically necessary if it is used with other noninvasive osteogenesis stimulators.

### **Coding Information**

The following list of codes are for informational purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

- E0747 Osteogenesis stimulator, electrical, noninvasive, other than spinal applications
- E0748 Osteogenesis stimulator, electrical, noninvasive, spinal applications
- E0749 Osteogenesis stimulator, electrical, surgically implanted
- E0760 Osteogenesis stimulator, low intensity ultrasound, non-invasive
- 20974 Electrical stimulation to aid bone healing; noninvasive (nonoperative)
- 20975 Electrical stimulation to aid bone healing; invasive (operative)
- 20979 Low intensity ultrasound stimulation to aid bone healing, noninvasive (nonoperative)

CPT® codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS® codes, descriptions and materials are copyrighted by Centers for Medicare and Medicaid Services (CMS).

#### References

American Academy of Orthopaedic Surgeons (AAOS) Nonunions. March 2014. Accessed Jan 9, 2015, April 17, 2017, March 1, 2018, February 28, 2019, December 3, 2019, October 12, 2020 <a href="http://orthoinfo.aaos.org/topic.cfm?topic=A00374">http://orthoinfo.aaos.org/topic.cfm?topic=A00374</a>

Busse, JW et al. Low Intensity Pulse Ultrasonography for Fractures: Systematic Review of Randomized Controlled Trials. British Medical Journal. 2009 February; 338(b351). Accessed January 10, 2014, March 1, 2018, February 28, 2019, December 3, 2019, October 12, 2020. http://www.bmj.com/content/338/bmj.b351

FDA Executive Summary: Prepared for the September 8-9, 2020 Meeting of the Orthopaedic and Rehabilitation Devices Panel. Reclassification of Non-Invasive Bone Growth Stimulators. (n.d.) FDA.Gov. Retrieved November 10, 2020, from https://www.fda.gov/media/141850/download

National Institute for Health and Clinical Excellence (NICE) Website. EXOGEN ultrasound bone healing system for long bone fractures with non-union or delayed healing: NICE medical technologies guidance [MTG12]. January 9, 2013. Accessed January 9, 2015, April 17, 2017, March 1, 2017, February 28, 2019, December 3, 2019,10/12/20 <a href="http://www.nice.org.uk/guidance/mtg12">http://www.nice.org.uk/guidance/mtg12</a>

Reznick DK, Choudhri TF, Dailey AT et al. Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 17: bone growth stimulators and lumbar fusion. *J Neurosurg Spine* 2005;2(6):737-40 Accessed on January 10, 2014, February 28, 2019, October 12, 2020 https://pubmed.ncbi.nlm.nih.gov/24980594/

Schofer, MD. et al. Improved healing response in delayed unions of the tibia with low-intensity pulsed ultrasound: results of a randomized sham-controlled trial. BMC Musculoskeletal Disorders 2010, 11:229. Accessed April 17, 2017, March 1, 2018, October 12, 2020. https://pubmed.ncbi.nlm.nih.gov/20932272/

# **Appendix**

**Policy Number:** 

**Effective:** 11/1/2020 **Next review:** 12/1/2021

Policy type: Enterprise

Author(s):

Depts: Health Services
Applicable regulation(s):
Commercial Ops: 10/2021
Government Ops: 10/2021