Bone Growth (Electronic and Ultrasonic) Stimulators

State(s):	LOB(s):
☒ *Idaho* ☒ *Montana* ☒ *Oregon* ☒ *Washington* ☐ *Other:*	☒ *Commercial* ☒ *Medicare* ☒ *Medicaid*

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

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

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):

- **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.
- **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.
- **Semi-invasive electronic bone growth stimulators** use direct current electrical stimulation via a percutaneous cathode and anode placed in contact with the skin.
- **Ultrasonic bone growth stimulators, using low intensity pulsed ultrasound**, are used to accelerate healing of fractures while receiving conventional treatment.

Criteria

Commercial

Ultrasonic bone growth stimulators must meet "Clinical Indications" listed in MCG™ ACG: A 0414

Bone Growth Stimulators, Ultrasonic.

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

1. Non-invasive electrical bone stimulation may be considered 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.

2. Invasive or non-invasive bone growth stimulators

Invasive or non-invasive EBGS may be considered medically necessary when ALL of the following criteria are met

- Adjunct to cervical or lumbar fusion **and**
- ONE or more of the following risk factors for failed fusion are present
  - One or more previously failed lumbar or cervical spinal fusion(s)
  - Grade III or worse spondylolisthesis
  - Fusion to be performed at more than one level
  - Current smoker
  - Diabetes
  - Renal disease
  - Poor nutrition, particularly protein deficiency

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

Medicaid

PacificSource Medicaid 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).

Note: **Bone Growth Stimulators** will be considered for rental only, as length of need cannot be determined or established in advance of the service.

Medicare

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

Exclusions all Lines of Business

- Use of an ultrasonic osteogenesis stimulator for the treatment of a fresh fracture or delayed union will be denied as not medically necessary
- An ultrasonic osteogenesis stimulator will be denied as not medically necessary if it is used with other noninvasive osteogenesis stimulators.

Coding Information

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)*

References

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Appendix

Policy Number: [Policy Number]

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

Policy type: Enterprise

Author(s): PD: 1/7/2021

Depts: Health Services

Applicable regulation(s):