



Bone Growth Stimulators

Clinical Coverage Criteria

Overview

Bone growth stimulation is the technique of promoting bone growth in difficult to heal fractures by applying an electrical current or ultrasound to the fracture. The theory behind applying an electric current to fractures to stimulate healing is based on the fact that the concave side of the bone becomes negatively charged and the convex side is positively charged. It is believed that artificially encouraging this charging with an electric current will speed healing.

An electrical bone growth stimulator (EBGS) is a device used to treat fractures with established nonunion; meaning, fractures with both clinical and radiological evidence of no progressive signs of healing. EBGSs are also indicated as an adjunct to cervical fusion surgery in patients at high risk for non-union/failed fusion. There are three types of electrical bone growth stimulators: invasive, semi-invasive and noninvasive.

- An invasive electrical stimulator is surgically implanted at the fracture site. The implantation is typically done at the time of a surgery to stabilize the fracture. Once the fracture has healed, the bone growth stimulation device is surgically removed. A major advantage of implantation is that therapy is provided constantly without the patient having to take an active role.
- A semi-invasive system which uses percutaneous cathodes that provide constant direct current is not currently in production.
- Non-invasive electrical stimulator systems use inductive coupling or capacitive coupling. With inductive coupling, pulsed electromagnetic fields (PEMFs) are delivered by a pair of external magnetic coils placed parallel to each other on top of the cast at the nonunion site. Treatment times vary from 10 to 16 hours per day. Because precise placement of the coils is necessary, the patient must remain relatively immobile during treatment.

An ultrasound bone growth stimulator (USBGS) is a device that is also used to treat fractures (fresh and nonunion). An USBGS provides low-intensity, pulsed ultrasound to the skin surface above fracture site. While the exact mechanism of ultrasound stimulation of bone healing is unknown, the theory is that the pressure waves it produces provides micro-mechanical stress and strain causing biochemical alterations at the cellular level, which leads to enhanced bone formation.

Policy

Fallon Health requires Prior Authorization for Bone Growth Stimulators. These requests must be supported by the treating provider(s) medical records.

For Commercial and Masshealth Plans:

Noninvasive nonspinal (HCPCS code E0747) is covered for the below conditions:

- Nonunion of long bone fractures in skeletally mature patients without serious systemic disease who are not taking steroids or other immunosuppressant's OR
- Congenital pseudoarthrosis

Noninvasive spinal (HCPCS code E0748) is covered for the below conditions:

- Failed arthrodesis, where a minimum of 6 months has elapsed since the last surgery and serial radiographs confirm there is no evidence of progression of healing for 3 months prior to starting treatment with the BGS; OR
- As an adjunct to arthrodesis for patients at high-risk for pseudoarthrosis *

Invasive (CPT code 20975 is used to report the implantation of an electric bone growth stimulator and HCPCS code E0749 is used to report the device) is covered for the below conditions:

- Nonunion of long bone fractures; OR
- As an adjunct to arthrodesis for patients at high risk for pseudoarthrosis* due to previously failed arthrodesis at the same site or for patients undergoing multilevel arthrodesis involving 3 or more vertebrae, OR
- As an adjunct to primary ankle or foot arthrodesis in patients at high risk of failure.

The below criteria must also be met:

- Patient must be 20 years of age or older OR demonstrate proof of skeletal maturity: AND
- The fracture gap is < 1 centimeter; AND
- For nonunion of long bone fractures, serial radiographs have confirmed that fracture healing has ceased for 3 or more months prior to starting treatment with the BGS, as demonstrated by:
 - A minimum of 2 sets of radiographs, each including multiple views of the fracture site, separated by a minimum of 90 days.

*High risk of pseudoarthrosis exists when

- Previously failed arthrodesis at the same site, OR
- Grade III or worse spondylolisthesis, OR
- Undergoing a multilevel fusion involving 3 or more vertebrae: e.g., L3-L5, L4-S1, etc.), OR
- Body mass index (BMI) of > 30 or who are greater than 50% over their ideal body weight, OR
- Diabetes, renal disease, or other metabolic diseases where bone healing is likely to be compromised or growth is poor, OR
- Nutritional deficiency, OR
- Severe anemia, OR
- Steroid therapy. OR
- Smoking.

HCPCS code E0760 (Osteogenic stimulator, low intensity ultrasound, non-invasive) is covered for the below conditions:

- Fresh, closed or Grade I open tibial diaphyseal fractures treated with closed reduction and cast immobilization in skeletally mature adult patients.

- Fresh, closed fracture of distal radius (Colles fracture) treated with closed reduction and cast immobilization
- Fresh fractures metatarsal, Jones Fracture.
- Fresh Fractures of the carpal navicular (scaphoid)
- Nonunions of bones other than the skull or vertebrae in skeletally mature patients and excluding those that are related to malignancy and there is documentation that healing has ceased or is not progressing.

The below criteria also must be met:

- Patient must be 20 years of age or older OR demonstrate proof of skeletal maturity: AND
- The fracture gap is < 1 centimeter; AND
- For nonunion fractures, serial radiographs have confirmed that fracture healing has ceased for 3 or more months prior to starting treatment with the BGS, as demonstrated by:
 - A minimum of 2 sets of radiographs, each including multiple views of the fracture site, separated by a minimum of 90 days, AND
 - The patient has failed at least one surgical or medical intervention for the treatment of the fracture

For Medicare Based Plans:

Noninvasive nonspinal (HCPCS code E0747) is covered for the below conditions:

- Nonunion of long bone fractures; OR
- Failed arthrodesis where a minimum of nine months has elapsed since the last surgery; OR
- Congenital pseudoarthrosis

Noninvasive spinal (HCPCS code E0748) is covered for the below conditions:

- Failed arthrodesis where a minimum of nine months has elapsed since the last surgery; OR
- Following a multilevel spinal fusion surgery; OR
- Following spinal fusion surgery where there is a history of a previously failed spinal fusion at the same site.

Invasive (CPT code 20975 is used to report implantation of an electric bone growth stimulator and HCPCS code E0749 is used to report the device) is covered for the below conditions:

- Nonunion of long bone fractures; OR
- As an adjunct to arthrodesis for patients at high risk of pseudoarthrosis due to previously failed arthrodesis at the same site or for those undergoing multiple level arthrodesis. A multiple level arthrodesis involves 3 or more vertebrae (e.g., L3-L5, L4-S1, etc.).
- For nonunion of long bone fractures, serial radiographs have confirmed that fracture healing has ceased for 3 or more months prior to starting treatment with the BGS, as demonstrated by:
 - A minimum of 2 sets of radiographs, each including multiple views of the fracture site, separated by a minimum of 90 days.

HCPCS code E0760 (Osteogenic stimulator, low intensity ultrasound, non-invasive) is covered for the below conditions:

- Nonunion of a fracture documented by a minimum of two sets of radiographs obtained prior to starting treatment with the osteogenesis stimulator, separated by a minimum of 90 days. Each radiograph set must include multiple views of the fracture site accompanied by a written interpretation by a physician stating that there has been no clinically significant evidence of fracture healing between the two sets of radiographs; and
- The fracture is not of the skull or vertebrae; and
- The fracture is not tumor related

Exclusions

- Any use of Bone Growth Stimulators other than outlined in this policy.
- Concurrent use of electrical (invasive or noninvasive) and ultrasound bone growth stimulators is not covered.

Codes

CPT code 20975 should be used to report the implantation of an electric bone growth stimulator (physician services) and HCPCS code E0749 should be used to report the implanted device.

CPT code 20974 and 20979 should be used to report noninvasive electric or ultrasound stimulation treatment performed by a physician to aid bone healing. It is not appropriate to report these codes for demonstration, measuring, and/or education related to an electric or ultrasound bone growth stimulation device.

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

References

1. Hayes, Inc. Hayes Directory Ultrasound Bone Growth Stimulation. Published September 3, 2015. Annual Review Completed August 23, 2018.
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3. Noridian Healthcare Solutions Inc. CMS Local Coverage Determination for Osteogenesis Stimulators (L33796). Last Revised July 1, 2017
4. Centers for Medicare and Medicaid Services. National Coverage Determination for Osteogenic Stimulators (150.2). Effective April 27, 2005
5. Bashardoust Tajali S, Houghton P, MacDermid JC, Grewal R. Effects of low-intensity pulsed ultrasound therapy on fracture healing: a systematic review and meta-analysis. *Am J Phys Med Rehabil.* 2012;91(4):349-367.

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8. Salem KH, Schmelz A. Low-intensity pulsed ultrasound shortens the treatment time in tibia distraction osteogenesis. *Int Orthop.* 2014;38(7):1477-1482.
9. Cook JJ, Summers NJ, Cook EA. Healing in the new millennium: bone stimulators: an overview of where we've been and where we may be heading. *Clin Podiatr Med Surg.* 2015;32(1):45-59.
10. 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. doi: 10.1136/bmj.j656.

Policy History

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