Medical Coverage Policy | Electrical Bone Growth Stimulation of the Appendicular Skeleton - Implantable and Semi-Implantable

EFFECTIVE DATE:10|01|2017
POLICY LAST UPDATED: 06|02|2021

OVERVIEW
In the appendicular skeleton (the appendicular skeleton includes the bones of the shoulder girdle, upper extremities, pelvis, and lower extremities), electrical stimulation (with either implantable electrodes or noninvasive surface stimulators) has been investigated for the treatment of delayed union, nonunion, and fresh fractures. This policy addresses only implantable and semi-invasive devices.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
Medicare Advantage Plans
The implantable electric bone growth stimulator is covered as the Centers for Medicare and Medicaid Services (CMS) has determined that it is medically necessary.

Note: Medicare policy is developed separately from Blue Cross and Blue Shield of Rhode Island (BCBSRI) policy. Medicare policy incorporates consideration of governmental regulations from CMS, such as national coverage determinations or local coverage determinations. In addition to benefit differences, CMS may reach different conclusions regarding the scientific evidence than does BCBSRI. Medicare and BCBSRI policies may differ. However, Medicare Advantage Plans members must be offered, at least, the same services that Medicare offers.

Commercial Products
Implantable electrical bone growth stimulator is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

Medicare Advantage Plans and Commercial Products
The semi-invasive electrical bone growth stimulator is not covered as there are no devices with U.S. Food and Drug Administration (FDA) approval or clearance.

COVERAGE
Benefits may vary between groups and contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement for applicable not medically necessary benefits/coverage.

BACKGROUND
In the appendicular skeleton, electrical stimulation has been primarily used to treat tibial fractures, and thus this technique has often been thought of as a treatment of the long bones. According to orthopedic anatomy, the skeleton consists of long bones, short bones, flat bones, and irregular bones. Long bones act as levels to facilitate motion, while short bones function to dissipate concussive forces. Short bones include those composing the carpus and tarsus. Flat bones, such as the scapula or pelvis, provide a broad surface area for attachment of muscles. Despite their anatomic classification, all bones are composed of a combination of cortical and trabecular (also called cancellous) bone. Each bone, depending on its physiologic function, has a

different proportion of cancellous to trabecular bone. At a cellular level, however, both bone types are composed of lamellar bone and cannot be distinguished microscopically.

Electrical and electromagnetic fields can be generated and applied to bones through the following methods:

- Surgical implantation of a cathode at the fracture site with the production of direct current electrical stimulation. Invasive devices require surgical implantation of a current generator in an intramuscular or subcutaneous space, while an electrode is implanted within the fragments of bone graft at the fusion site. The implantable device typically remains functional for 6 to 9 months after implantation, and, although the current generator is removed in a second surgical procedure when stimulation is completed, the electrode may or may not be removed. Implantable electrodes provide constant stimulation at the nonunion or fracture site but carry increased risks associated with implantable leads.
- Semi-invasive (semi-implantable) stimulators use percutaneous electrodes and an external power supply obviating the need for a surgical procedure to remove the generator when treatment is finished. No semi-invasive electrical bone growth stimulator devices with FDA approval or clearance were identified.

For individuals who have fracture, pseudoarthroses, or who have had surgery of the appendicular skeleton who receive implantable and semi-invasive electrical bone growth stimulation, the evidence includes a small number of case series. Relevant outcomes are symptoms, change in disease status, and functional outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes

Medicare Advantage Plans
CMS has a National Coverage Determination (NCD) which states that the invasive stimulator device is covered only for the following indications:

- Nonunion of long bone fractures;
- Effective July 1, 1996, as an adjunct to spinal fusion surgery for patients at high risk of pseudarthrosis due to previously failed spinal fusion at the same site or for those undergoing multiple level fusion. A multiple level fusion involves 3 or more vertebrae (e.g., L3-L5, L4-S1, etc.).
- Effective September 15, 1980, nonunion of long bone fractures is considered to exist only after 6 or more months have elapsed without healing of the fracture.
- Effective April 1, 2000, nonunion of long bone fractures is considered to exist only when starting treatment with the electrical osteogenic stimulator. Serial radiographs must include a minimum of 2 sets of radiographs, each including multiple views of the fracture site, separated by a minimum of 90 days.

Based on this coverage determination, the invasive(implantable) stimulator will be covered.

CODING

The following code is covered for Medicare Advantage Plans and not medically necessary for Commercial products:
20975 Electrical stimulation to aid bone healing; invasive (operative)
E0749 Osteogenesis stimulator, electrical, surgically implanted

Note - There is no code for the semi-invasive stimulator as there is not an FDA approved device.

RELATED POLICIES

Preauthorization via Web-Based Tool for Durable Medical Equipment (DME)

PUBLISHED

Provider Update August 2021

Provider Update August 2020
Provider Update November 2019
Provider Update September 2018
Provider Update December 2017

REFERENCES

1. U.S. Food and Drug Administration (FDA). Summary Minutes: Center for Devices and Radiological Health Orthopaedic and Rehabilitation Devices Panel. 2020; https://www.fda.gov/media/145157/download. Accessed March 8, 2021.
2. Bhandari M, Fong K, Sprague S, et al. Variability in the definition and perceived causes of delayed unions and nonunions: a cross-sectional, multinational survey of orthopaedic surgeons. J Bone Joint Surg Am. Aug 01 2012; 94(15): e1091-6. PMID 22854998
3. Buza JA, Einhorn T. Bone healing in 2016. Clin Cases Miner Bone Metab. May-Aug 2016; 13(2): 101-105. PMID 27920804
4. Ahl T, Andersson G, Herberts P, et al. Electrical treatment of non-united fractures. Acta Orthop Scand. Dec 1984; 55(6): 585-8. PMID 6335345
5. Connolly JF. Selection, evaluation and indications for electrical stimulation of ununited fractures. Clin Orthop Relat Res. Nov-Dec 1981; (161): 39-53. PMID 6975690
6. Connolly JF. Electrical treatment of nonunions. Its use and abuse in 100 consecutive fractures. Orthop Clin North Am. Jan 1984; 15(1): 89-106. PMID 6607443
7. de Haas WG, Beaupre A, Cameron H, et al. The Canadian experience with pulsed magnetic fields in the treatment of ununited tibial fractures. Clin Orthop Relat Res. Jul 1986; (208): 55-8. PMID 3720140
8. Sharrard WJ, Sutcliffe ML, Robson MJ, et al. The treatment of fibrous non-union of fractures by pulsing electromagnetic stimulation. J Bone Joint Surg Br. 1982; 64(2): 189-93. PMID 6978339
9. Aleem IS, Aleem I, Evaniew N, et al. Efficacy of Electrical Stimulators for Bone Healing: A Meta-Analysis of Randomized Sham-Controlled Trials. Sci Rep. Aug 19 2016; 6: 31724. PMID 27539550
10. Simonis RB, Parnell EJ, Ray PS, et al. Electrical treatment of tibial non-union: a prospective, randomised, double-blind trial. Injury. May 2003; 34(5): 357-62. PMID 12719164
11. Barker AT, Dixon RA, Sharrard WJ, et al. Pulsed magnetic field therapy for tibial non-union. Interim results of a double-blind trial. Lancet. May 05 1984; 1(8384): 994-6. PMID 6143970
12. Scott G, King JB. A prospective, double-blind trial of electrical capacitive coupling in the treatment of non-union of long bones. J Bone Joint Surg Am. Jun 1994; 76(6): 820-6. PMID 8200888
13. Shi HF, Xiong J, Chen YX, et al. Early application of pulsed electromagnetic field in the treatment of postoperative delayed union of long-bone fractures: a prospective randomized controlled study. BMC Musculoskelet Disord. Jan 19 2013; 14: 35. PMID 23331333
14. Sharrard WJ. A double-blind trial of pulsed electromagnetic fields for delayed union of tibial fractures. J Bone Joint Surg Br. May 1990; 72(3): 347-55. PMID 2187877
15. Griffin XL, Warner F, Costa M. The role of electromagnetic stimulation in the management of established non-union of long bone fractures: what is the evidence?. Injury. Apr 2008; 39(4): 419-29. PMID 18321512
16. Griffin XL, Costa ML, Parsons N, et al. Electromagnetic field stimulation for treating delayed union or non-union of long bone fractures in adults. Cochrane Database Syst Rev. Apr 13 2011; (4): CD008471. PMID 21491410
17. Adie S, Harris IA, Naylor JM, et al. Pulsed electromagnetic field stimulation for acute tibial shaft fractures: a multicenter, double-blind, randomized trial. J Bone Joint Surg Am. Sep 07 2011; 93(17): 1569-76. PMID 21915570
18. Faldini C, Cadossi M, Luciani D, et al. Electromagnetic bone growth stimulation in patients with femoral neck fractures treated with screws: prospective randomized double-blind study. Curr Orthop Pract. 2010;21(3):282- 287.
19. Hannemann PF, Gottgens KW, van Wely BJ, et al. The clinical and radiological outcome of pulsed electromagnetic field treatment for acute scaphoid fractures: a randomised double-blind placebo-controlled multicentre trial. J Bone Joint Surg Br. Oct 2012; 94(10): 1403-8. PMID 23015569

20. Hannemann PF, van Wezenbeek MR, Kolkman KA, et al. CT scan-evaluated outcome of pulsed electromagnetic fields in the treatment of acute scaphoid fractures: a randomised, multicentre, double-blind, placebo-controlled trial. Bone Joint J. Aug 2014; 96-B(8): 1070-6. PMID 25086123
21. Martinez-Rondanelli A, Martinez JP, Moncada ME, et al. Electromagnetic stimulation as coadjuvant in the healing of diaphyseal femoral fractures: a randomized controlled trial. Colomb Med (Cali). Apr-Jun 2014; 45(2): 67-71. PMID 25100891
22. Beck BR, Matheson GO, Bergman G, et al. Do capacitively coupled electric fields accelerate tibial stress fracture healing? A randomized controlled trial. Am J Sports Med. Mar 2008; 36(3): 545-53. PMID 18055921
23. Borsalino G, Bagnacani M, Bettati E, et al. Electrical stimulation of human femoral intertrochanteric osteotomies. Double-blind study. Clin Orthop Relat Res. Dec 1988; (237): 256-63. PMID 3191636
24. Dhawan SK, Conti SF, Towers J, et al. The effect of pulsed electromagnetic fields on hindfoot arthrodesis: a prospective study. J Foot Ankle Surg. Mar-Apr 2004; 43(2): 93-6. PMID 15057855
25. Petrisor B, Lau JT. Electrical bone stimulation: an overview and its use in high risk and Charcot foot and ankle reconstructions. Foot Ankle Clin. Dec 2005; 10(4): 609-20, vii-viii. PMID 16297822
26. Lau JT, Stamatis ED, Myerson MS, et al. Implantable direct-current bone stimulators in high-risk and revision foot and ankle surgery: a retrospective analysis with outcome assessment. Am J Orthop (Belle Mead NJ). Jul 2007; 36(7): 354-7. PMID 17694182
27. Saxena A, DiDomenico LA, Widtfeldt A, et al. Implantable electrical bone stimulation for arthrodeses of the foot and ankle in high-risk patients: a multicenter study. J Foot Ankle Surg. Nov-Dec 2005; 44(6): 450-4. PMID 16257674
28. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Osteogenic Stimulators (150.2). 2005; https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=65&ncdver=2&DocID=150.2&ncd_id=150.2&ncd_version=2&basket=ncd%2525 3A150%25 252E2%25253A2%25253AOsteogenic+Stimulators&bc=gAAAABAAAAAA&. Accessed March 8, 2021.