

OHCA Guideline

Medical Procedure Class:	Osteogenic Stimulators
Initial Implementation Date:	06/01/2021
Last Review Date:	05/25/2021
Effective Date:	06/01/2021
Next Review/Revision Date:	06/01/2024
* This document is not a contract, and these guidelines do not reflect or represent every conceivable situation. Although all items contained in these guidelines may be met, this does not reflect, or imply, any responsibility of this agency or department to change the plan provision to include the stated service as an eligible benefit.	
<input checked="" type="checkbox"/> New Criteria <input type="checkbox"/> Revision of Existing Criteria	
Summary	
Purpose:	To provide guidelines to assure medical necessity and consistency in the prior authorization process.
Definitions	
<p>Long bone- limited to a clavicle, humerus, radius, ulna, femur, tibia, fibula, metacarpal, or metatarsal</p> <p>Multi-level spinal fusion- spinal fusion that involves 3 or more vertebrae (e.g., L3-L5, L4-S1, etc.)</p> <p>Non-union- failure of normal healing of a fractured bone</p> <p>Osteogenic- derived from or composed of any tissue concerned in bone growth or repair</p> <p>Pseudarthroses- a false joint arising at the site of an ununited fracture</p> <p>Spondylolisthesis- forward displacement of one of the lower lumbar vertebrae over the vertebra below it or on the sacrum.</p>	
Description	
<p>Bone growth stimulation is utilized to promote bone healing in difficult to heal fractures or fusions by applying electrical or ultrasonic current to the fracture or fusion site.</p> <p>Electrical stimulation to augment bone repair can be attained from inside the body (invasive) or from outside the body (non-invasive). Invasive devices provide electrical stimulation directly at the fracture site through percutaneously placed cathodes or by implantation of a coiled cathode wire into the fracture site. The power pack is also implanted into soft tissue near the fracture site creating a self-contained system. Non-invasive devices have opposing pads, wired to an external power supply. The pads are placed externally around the fracture or fusion site or placed over a cast to create an electromagnetic field.</p> <p>Ultrasonic stimulation is a non-invasive device that emits low intensity, pulsed ultrasound signals to the skins surface at the fracture location using ultrasound and coupling gel to stimulate healing.</p>	
CPT Codes Covered Requiring Prior Authorization (PA)	
<p>20974- Electrical stimulation to aid bone healing; non-invasive (non-operative)</p> <p>20975- Electrical stimulation to aid bone healing; invasive (operative)</p> <p>20979- Low intensity ultrasound stimulation to aid bone healing, non-invasive (non-operative)</p> <p>E0747- Osteogenesis stimulator, electrical, non-invasive, other than spinal applications</p> <p>E0748- Osteogenesis stimulator, electrical, noninvasive spinal applications</p> <p>E0749- Osteogenesis stimulator, electrical, surgically implanted</p>	

Approval Criteria

I. GENERAL

- A. Medical necessity must be met, all documentation submitted to request services or substantiate previously provided services must demonstrate through adequate objective medical records, evidence sufficient to justify the member's needs for the service in accordance with the OAC 317:30-3-1, 317:30-5-211.3, 317:30-5-211.10
- B. Certificate of Medical Necessity (CMN) completed by the prescribing physician or non-physician practitioner (MD, DO, PA, CNP, ARNP).
- C. All documentation must be easily legible.

II. INDICATIONS

A. **Electrical Bone Stimulators: Invasive/Non-invasive, Spinal or Non-spinal** **NON-INVASIVE**

- 1. Delayed unions of fractures or failed arthrodesis at high-risk sites (i.e., open or segmental tibial fractures, carpal navicular fractures, 5th metatarsal fractures, distal radius), **OR**
- 2. Failed fusion of a joint (spinal or non-spinal) where a minimum of nine months has elapsed since the last surgery, **OR**
- 3. Following a multi-level spinal fusion surgery, **OR**
- 4. As an adjunct to spinal fusion surgery for patients at high risk of pseudarthrosis (e.g. previously failed spinal fusion at the same site, smoking, alcoholism, diabetes, immunosuppressant medications, or older age), **OR**
- 5. Grade II or worse spondylolisthesis, **OR**
- 6. Congenital pseudarthrosis, **OR**
- 7. Non-union of long bone fractures when the following criteria are met:
 - a. Fracture healing has ceased for 3 or more months confirmed with a minimum of 2 sets of radiographs, obtained prior to starting treatment with bone stimulator, at a minimum of 90 days apart. Each radiograph set must include multiple views of the fracture site with written physician interpretation stating there has been no significant evidence of fracture healing between the two sets, despite appropriate fracture care, **AND**
 - b. Bone is noninfected, **AND**
 - c. Bone is stable on both ends by means of cast or fixation, **AND**
 - d. The two portions of the involved bone are separated by ≤ 1 centimeter (cm).

INVASIVE

- 1. Following a multi-level spinal fusion surgery, **OR**
- 2. As an adjunct to spinal fusion surgery for patients at high risk of pseudarthrosis (e.g. previously failed spinal fusion at the same site, smoking, alcoholism, diabetes, immunosuppressant medications, or older age), **OR**
- 3. Non-union of long bone fractures when the following criteria are met:
 - a. Fracture healing has ceased for 3 or more months confirmed with a minimum of 2 sets of radiographs, obtained prior to starting treatment with bone stimulator, at a minimum of 90 days apart. Each radiograph set must include multiple views of the fracture site with written physician interpretation stating there has been no significant evidence of fracture healing between the two sets, despite appropriate fracture care.

B. Ultrasonic Bone Stimulators

1. Non-union of a fracture documented by a minimum of two sets of radiographs obtained prior to starting treatment with the bone stimulator, at a minimum of 90 days apart. Each radiograph set must include multiple views of the fracture site with written physician interpretation stating there has been no significant evidence of fracture healing between the two sets, despite appropriate fracture care, **AND**
2. The fracture is not of the skull or vertebrae, **AND**
3. The fracture is not tumor related, **AND**
4. Fracture gap is ≤ 1 cm

****Note:** Additional information may be required after initial review**

Additional Information

Ultrasonic osteogenic stimulators may not be used concurrently with other non-invasive osteogenic devices.

Ultrasonic osteogenic stimulators for fresh fractures and delayed unions are non-covered.

E0760- Osteogenesis stimulator, low intensity ultrasound, non-invasive—No PA requirement at this time

References

1. Oklahoma Health Care Authority, Policies and Rules, OAC 317:30-1
2. National Coverage Determination (NCD) Osteogenic Stimulators (150.2) 2005. Retrieved from: <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=65>
3. Local Coverage Determination (LCD) Osteogenesis Stimulators (L33796) 01/01/2020. Retrieved from: <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?lcdid=33796&ver=17&keyword=osteogenesis%20stimulators&keywordType=starts&areald=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=AAAAAAQAAAA&KeyWordLookUp=Doc&KeyWordSearchType=Exact>
4. Farlex Partner Medical Dictionary. Farlex 2012. The Free Dictionary by Farlex. Accessed at: <https://medical-dictionary.thefreedictionary.com>
5. Cigna Medical Coverage Policy. Bone Growth Stimulators: Electrical (Invasive, Noninvasive), Ultrasound. Retrieved from: https://static.cigna.com/assets/chcp/pdf/coveragePolicies/medical/mm_0084_coveragepositioncriteria_bone_growth_stimulators.pdf
6. United Health Care Medicare Advantage. Osteogenic Stimulators (NCD 150.2). Guideline number MPG226.06 09/09/2020. Retrieved from: <https://www.uhcprovider.com/content/dam/provider/docs/public/policies/medadv-guidelines/o/osteogenic-stimulators.pdf>
7. Hayes. Electrical Bone Growth Stimulation, Invasive. July 2016. Retrieved from: <https://evidence.hayesinc.com/report/dir.electricalinvasive167>