**Coverage Statement:** Osteogenic stimulators are covered in accordance with Medicare coverage criteria.

**Note: DME Face to Face Requirement:** Effective July 1, 2013, Section 6407 of the Affordable Care Act (ACA) established a face-to-face encounter requirement for certain items of DME (including electric and low intensity osteogenesis stimulators). For DME Face to Face Requirement information, refer to the Durable Medical Equipment (DME), Prosthetics, Corrective Appliances/Orthotics (Non-Foot Orthotics) and Medical Supplies Grid

**Guidelines/Notes:**

1. **Electrical Osteogenic Stimulator**
   a. **Invasive (Implantable) Stimulator (HCPCS code E0749)**
      
      The invasive stimulator device is covered only for the following indications:
      
      1) Nonunion of long bone fractures;
2) 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 fusions. A multiple level fusion involves 3 or more vertebrae (e.g., L3-L5, L4-S1, etc).

3) Effective April 1, 2000, nonunion of long bone fractures is considered to exist only when serial radiographs have confirmed that fracture healing has ceased for 3 or more months prior to 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.

b. Noninvasive Stimulator (HCPCS codes E0747 and E0748)

The noninvasive stimulator device is covered only for the following indications:

1) Nonunion of long bone fractures;
2) Failed fusion, where a minimum of 9 months has elapsed since the last surgery;
3) Congenital pseudarthroses;
4) 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 fusions. A multiple level fusion involves 3 or more vertebrae (e.g., L3-L5, L4-S1, etc).

5) Effective April 1, 2000, nonunion of long bone fractures is considered to exist only when serial radiographs have confirmed that fracture healing has ceased for 3 or more months prior to 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.

2. Ultrasonic Osteogenic Stimulator (HCPCS code E0760)

a. Effective April 27, 2005, noninvasive ultrasound stimulators are covered as medically reasonable and necessary for the treatment of nonunion bone fractures prior to surgical intervention. In demonstrating non-union fractures, the following must be met:

A minimum of 2 sets of radiographs, obtained prior to starting treatment with the osteogenic stimulator, separated by a minimum of 90 days.

Each radiograph set must include multiple views of the fracture site accompanied with a written interpretation by a physician stating that there has been no clinically significant evidence of fracture healing between the 2 sets of radiographs.

b. Non-invasive ultrasonic stimulator is not covered for any of the following:

1) Nonunion fractures of the skull, vertebrae and those that are tumor related
2) Fresh fractures and delayed unions
3) For use concurrently with other non-invasive osteogenic devices

See the National Coverage Determination (NCD) for Osteogenic Stimulators (150.2). (Accessed August 29, 2018)

Local Coverage Determination (LCD) exists and compliance with this policy is required where applicable. See the DME MAC LCD for Osteogenesis Stimulators (L33796). (Accessed August 29, 2018)
II. DEFINITIONS

Long Bone: The definition of "long bone" is limited to the following bones: clavicle, humerus, radius, ulna, femur, tibia, fibula, metacarpal, or metatarsal bones. DME MAC LCD for Osteogenesis Stimulators (L33796). (Accessed August 29, 2018)

Osteogenic Stimulators: Devices that use electrical stimulation to augment bone repair. There are two types of osteogenic stimulators: Invasive stimulations that directly stimulate a fracture site through an implanted electrode and connected to a power pack. Non-invasive devices use opposing pads over the cast and the electrodes are then connected to a power source creating an energy field over the fracture. NCD for Osteogenic Stimulators (150.2) (Accessed August 29, 2018)

Ultrasonic Osteogenic Stimulator: A device that emits low intensity pulsed sound waves. The device is applied to the skin at the fracture site and through conduction gel emits pulsed sound waves over the fracture site to stimulate healing. NCD for Osteogenic Stimulators (150.2) (Accessed August 29, 2018)

III. REFERENCES

See above

IV. REVISION HISTORY

04/01/2019  Updated policy introduction; added language to clarify:
- There are instances where [the Coverage Summary] may direct readers to a UnitedHealthcare Commercial Medical Policy, Medical Benefit Drug Policy, and/or Coverage Determination Guideline (CDG)
- In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5)

09/18/2018  Annual review; no updates

09/19/2017  Annual review with the following updates:
- Guideline 1 and 2 - moved the references to the end guideline section; no change in references
- Guideline 3 [Professional Fees (CPT codes 20974, 20975 and 20979)] – deleted guideline; the only LCD reference, i.e., [First Coast LCD for Osteogenic Stimulation (L33928)] was retired; no other available LCD or Medicare reference found.
- Definitions
  - Long Bone – changed reference from NCD for Osteogenic Stimulators (150.2) to DME MAC LCD for Osteogenesis Stimulators (L33796)
  - Osteogenic Stimulators – added “Devices that use electrical stimulation to augment bone repair”
  - Ultrasonic Osteogenic Stimulator – changed reference from LCD for Osteogenic Stimulation (L33928) to NCD for Osteogenic Stimulators (150.2)

09/20/2016  Annual review; no updates
10/20/2015  Annual review; no updates

10/21/2014  Annual review with the following updates:
            Removed detailed DME Face-to-Face Requirement information and replaced with a reference link to the DME, Prosthetics, Corrective Appliances/Orthotic and Medical Supplies Grid
            Definitions:
            Long Bone - Added reference link to the NCD for Osteogenic Stimulators (150.2)
            Osteogenic Stimulators - Added reference link to the NCD for Osteogenic Stimulators (150.2)
            Ultrasonic Osteogenic Stimulator - Added reference link to the LCD for Osteogenic Stimulation (L29375)

04/15/2014  **Guideline #1 (Electrical Osteogenic Stimulator)**
            Deleted from #1.a.2 and #1.b.4 “Effective July 1, 1996”
            Deleted “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

**Guideline #2 (Ultrasonic Osteogenic Stimulator)**
            Deleted from #2.a the following:
            **Effective January 1, 2001, ultrasonic osteogenic stimulators are covered as medically reasonable and necessary for the treatment of nonunion fractures. In demonstrating nonunion fractures, the following must be met:**
            **A minimum of 2 sets of radiographs, obtained prior to starting treatment with the osteogenic stimulator, separated by a minimum of 90 days. Each radiograph set must include multiple views of the fracture site accompanied with a written interpretation by a physician stating that there has been no clinically significant evidence of fracture healing between the 2 sets of radiographs; and,**
            **Indications that the patient failed at least one surgical intervention for the treatment of the fracture**
            Added to #2.a (second bullet point) the following:
            **significant evidence of fracture healing between the 2 sets of radiographs**

10/24/2013  Annual review; no updates

08/20/2013  Added a note pertaining to the DME Face-to-Face Requirement in accordance with Section 6407 of the Affordable Care Act as defined in the 42 CFR 410.38(g)

10/31/2012  Annual review; updated to include Guidelines #9 - Professional Fees

10/13/2011  Policy updated based on the current coverage language of the NCD for Osteogenic Stimulators (150.2)

02/21/2011  Annual review; no updates