Coverage Summary

Stimulators: Osteogenic Stimulators

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<td>Approved by: UnitedHealthcare Medicare Benefit Interpretation Committee</td>
<td>Last Review Date: 09/17/2019</td>
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<tr>
<td>Related Medicare Advantage Policy Guideline: Osteogenic Stimulators (NCD 150.2)</td>
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The benefit information in this Coverage Summary is based on existing national coverage policy, however, Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable.

There are instances where this document 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).

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   1. Electrical Osteogenic Stimulator
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I. COVERAGE

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 Coverage Summary for 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.
   b. 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.
   c. 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 23, 2019)*

*Local Coverage Determination (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. See the DME MAC LCDs/LCAs for Osteogenesis*
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 23, 2019)

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 23, 2019)

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 23, 2019)

III. REFERENCES

See above

IV. REVISION HISTORY

09/17/2019  •  Routine review; no change to coverage guidelines