Policy References: Local Coverage Determination Osteogenesis Stimulators (L33796) and Policy Article (A52513)

Documentation References: Standard Documentation Requirements Policy Article (PA) A55426

The supplier must be able to provide all of these items on request:

- Standard Written Order (SWO)
- Beneficiary Authorization
- Proof of Delivery (POD)
- Continued Need
- Continued Use
- Certificate of Medical Necessity (CMN) CMS-847
- Medical records from treating practitioner as noted below

Medical Records should contain:

Non-spinal Electrical Osteogenesis Stimulator (OS) (E0747) is only covered if any of the following criteria are met:

- Nonunion of a long bone (clavicle, humerus, radius, ulna, femur, tibia, fibula, metacarpal, or metatarsal) fracture defined as x-ray evidence that fracture healing has ceased for three or more months prior to starting treatment with the OS; or

- Failed fusion of a joint other than in the spine where a minimum of nine months has elapsed since the last surgery; or

- Congenital pseudarthrosis

- Nonunion of a long bone fracture must be documented by a minimum of two sets of x-rays obtained prior to starting treatment, separated by a minimum of 90 days, each including multiple views of the fracture site, and with a written interpretation by a physician stating there has been NO clinically significant evidence of fracture healing between the two sets of x-rays

Spinal Electrical OS (E0748) is covered only if any of the following criteria are met:

- Failed spinal fusion where a minimum of nine months has elapsed since the last surgery; or

- Following a multilevel (three or more vertebrae) spinal fusion surgery; or

- Following spinal fusion surgery, there is a history of a previously failed spinal fusion at the same site

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Ultrasonic OS (E0760) is covered only if all of the following criteria are met:

- Nonunion of a fracture documented by a minimum of two sets of x-rays obtained prior to starting treatment with the OS, separated by a minimum of 90 days. Each x-ray 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 x-rays; and

- Fracture is not of the skull or vertebrae; and

- Fracture is not tumor related.