Medical Necessity Guideline

Medical Necessity Guideline (MNG) Title: Osteogenesis Stimulators		
MNG #: 065	**☒SCO ☒One Care** **☒ MAPD-MA Medicare Preferred** **☒ MAPD-MA Medicare Value** **☒ MAPD-RI Medicare Preferred** **☒ MAPD-RI Medicare Value** **☒ DSNP-RI Medicare Maximum**	**Prior Authorization Needed?** **☒Yes ☐No**
Clinical: ☒	**Operational: ☐**	**Informational: ☐**
Medicare Benefit: **☒Yes ☐No**	**Approval Date:** 4/1/2021;	**Effective Date:** 06/19/2021
Last Revised Date:	**Next Annual Review Date:** 4/1/2022;	**Retire Date:**

OVERVIEW:

An osteogenesis stimulator is a specific DME designed to encourage bone growth and healing. The device delivers a small electrical current or pulses of ultrasound across a gap between fractured bone ends. Originally an implantable device, these devices are now commonly external devices applied to intact skin with a battery and controller and skin pads applied above and below or over the area of bone break. The stimulus may be an older constant voltage design or a newer variable, pulsed, even nonlinear changing electrical voltage. Electrical devices are more effective than ultrasonic ones. Implantable devices are now seldom used, and implantable devices are not ordinarily covered. Members may need training in the use of their stimulator. This training should be carried out by a professional normally in an orthopedist's office who is certified or licensed in the prescription and use of this equipment. With the exception of wire leads and pads, these devices often cannot be repaired or modified. In case of failure, there should be consideration of replacement with a properly functioning unit.

CLINICAL COVERAGE CRITERIA:

Non-spinal Osteogenesis Stimulator (E0747): CCA may approve coverage for non-spinal Osteogenesis Stimulator osteogenesis stimulators when **one (1)** of the following criteria are met:

1. Nonunion of a long bone fracture (clavicle, humerus, radius, ulna, femur, tibia, fibula, metacarpal, or metatarsal) as defined as radiographic evidence that bone fracture healing has ceased for, at a minimum, ninety (90) days, or
2. Failed fusion of a joint other than in the spine where a minimum of nine (9) months have elapsed since the last surgery, or
3. Congenital pseudoarthrosis

Nonunion of a long bone fracture must be documented by a minimum of two sets of radiographs obtained prior to starting treatment with the osteogenesis stimulator, separated by a minimum of 90 days, each including multiple views

of the fracture site, and with a written interpretation by a treating practitioner stating that there has been no clinically significant evidence of fracture healing between the two sets of radiographs.

Spinal electrical osteogenesis stimulator (E0748): CCA may approve coverage for spinal electrical osteogenesis stimulators when **one (1)** of the following criteria are met:

1. Failed spinal fusion where a minimum of nine months has elapsed since the last surgery, or
2. Following a multilevel spinal fusion surgery (i.e., one which involves 3 or more vertebrae [e.g., L3-L5, L4-S1, etc]), or
3. Following spinal fusion surgery where there is a history of a previously failed spinal fusion at the same site.

Ultrasonic osteogenesis stimulator (E0760): CCA may approve coverage for spinal electrical osteogenesis stimulators when **all** of the following criteria are met:

1. Nonunion of a fracture as defined as radiographic evidence that bone fracture healing has ceased for, at a minimum, ninety (90) days; and
2. The fracture is not of the skull or vertebrae; and
3. The fracture is not tumor related.

Prior authorization requests must include:

1. Nonunion of a long bone fracture must be documented by a minimum of two sets of radiographs obtained prior to starting treatment with the osteogenesis stimulator, separated by a minimum of 90 days, each including multiple views of the fracture site, and with a written interpretation by a treating practitioner stating that there has been no clinically significant evidence of fracture healing between the two sets of radiographs.
2. Quotation of the supplier's charges in accordance with their CCA contract.

Determination of need:

N/A

LIMITATIONS/EXCLUSIONS:

1. An ultrasonic osteogenesis stimulator will be denied as not medically necessary if it is used with other noninvasive osteogenesis stimulators.
2. Use of an ultrasonic osteogenesis stimulator for the treatment of a fresh fracture or delayed union will be denied as not medically necessary.
3. An ultrasonic osteogenesis stimulator will be denied as not medically necessary if it is used with other noninvasive osteogenesis stimulators.
4. This device must be obtained from an in-network vendor. Out of Network vendor devices are not covered services when similar in network devices are available.

KEY CARE PLANNING CONSIDERATIONS:

- Is the bone gap < 1 cm in width? (Preferably Yes)
- Has the member shown potential to use the equipment appropriately?
- Will training result in the member's independent use of the equipment?

- Has the member's status changed since receiving this equipment?
- Has the member stopped wearing this equipment due to weight, chafe, annoyance, memory loss, or change in their personal care planning?
- What are the consequences of not having this equipment worn?
- Has this piece of equipment broken more than once?
- If so, does the member need to be re-evaluated for a more appropriate piece of equipment that will meet their needs without breakage?

AUTHORIZATION:

N/A

RELATED REFERENCES:

References:

Local Coverage Determination (LCD): Osteogenesis Stimulators (L33796). Original effective date 10/1/2015, revision effective date 1/1/2020. https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?lcdid=33796&ver=17&KeyWord=stimulator&KeyWordLookUp=Title&KeyWordSearchType=Exact&bc=CAAAAAAAAAAA. Accessed 3/29/2021.

Griffin XL, Costa ML, Parsons N, Smith N. Electromagnetic field stimulation for treating delayed union or non-union of long bone fractures in adults. Cochrane Database of Systematic Reviews 2011, Abstract

ATTACHMENTS:

EXHIBIT A	
EXHIBIT B	

REVISION LOG:

REVISION DATE	DESCRIPTION

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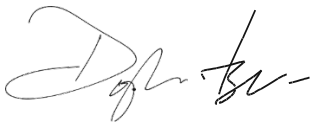
APPROVALS:

Douglas Hsu, MD	Vice President, Medical Policy and Utilization Management
CCA Senior Clinical Lead [Print]	**Title [Print]**
	4/1/2021
Signature	**Date**
Click here to enter text.	
CCA Senior Operational Lead [Print]	**Title [Print]**
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Lori Tishler, MD	Sr. Vice President, Medical Services
CCA CMO or Designee [Print]	**Title [Print]**
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