Medical Policy

Northwood

Osteogenesis Stimulators – Spinal and Non-Spinal

Description

An electrical osteogenesis stimulator is a device that provides electrical stimulation to promote bone repair. A noninvasive electrical stimulator consists of an electric control module which applies programmed electromagnetic pulses through a coil or electrodes placed on the skin or on a cast or brace over a fracture or fusion site.

An ultrasonic osteogenesis stimulator is a non-invasive device that uses a low intensity pulsed ultrasound. The ultrasound signal is applied to the skin surface at the fracture location via ultrasound conductive coupling gel in order to stimulate fracture healing.

Policy

An osteogenesis stimulator (spinal/non-spinal electric and ultrasonic) is considered **reasonable and necessary** when a member meets the coverage criteria.

Policy Guidelines

Coverage Criteria:

1. Must be ordered by the member's treating practitioner.

Non-spinal electrical osteogenesis stimulator (E0747) is considered reasonable and necessary only if any of the following criteria are met:

1. Nonunion of a long bone fracture (see Appendices section) defined as radiographic evidence that fracture healing has ceased for three or more months prior to starting treatment with the osteogenesis stimulator, or

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

3. Congenital pseudarthrosis

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 physician stating that there has been no clinically significant evidence of fracture healing between the two sets of radiographs.

A non-spinal electrical osteogenesis stimulator will not be considered reasonable and necessary if the listed criteria above are not met.

A **spinal electrical osteogenesis stimulator (E0748)** is covered only if any 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 (see Appendices section), or

3. Following spinal fusion surgery where there is a history of a previously failed spinal fusion at the same site.

A spinal electrical osteogenesis stimulator will not be considered reasonable and necessary if none of the criteria above are met.

An **ultrasonic osteogenesis stimulator (E0760)** may be considered reasonable and necessary ONLY if all of the following criteria are met:

a. The nonunion of the fracture is documented by a minimum of two 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 by a written interpretation by a physician stating that there has been no clinically significant evidence of fracture healing between the two sets of radiographs; and
b. The fracture is not of the skull or vertebrae; and
c. The fracture is not tumor related.

An osteogenesis stimulator will be denied as not medically necessary if any of the criteria above are not met.

Use of an ultrasonic osteogenesis stimulator for the treatment of a fresh fracture or delayed union will be considered not reasonable and necessary.

Ultrasound conductive coupling gel is covered and separately payable if an ultrasonic osteogenesis stimulator is covered.

An ultrasonic osteogenesis stimulator will be denied as not reasonable and necessary if it is used with other noninvasive osteogenesis stimulators.

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HCPCS Level II Codes and Description

Equipment:

E0747	OSTEOGENESIS STIMULATOR, ELECTRICAL, NON-INVASIVE, OTHER THAN SPINAL APPLICATIONS
E0748	OSTEOGENESIS STIMULATOR, ELECTRICAL, NON-INVASIVE, SPINAL APPLICATIONS
E0760	OSTEOGENESIS STIMULATOR, LOW INTENSITY ULTRASOUND, NON-INVASIVE

Supplies:

A4559	COUPLING GEL OR PASTE, FOR USE WITH ULTRASOUND DEVICE, PER OZ

Documentation Requirements

Items in this policy may be subject to the Affordable Care Act (ACA) 6407.

The Affordable Care Act (ACA) 6407 requires that the treating practitioner conduct a face-to-face examination during the six month period preceding the written order. The documentation must be received by the provider prior to delivery for certain DME items. The documentation must describe a medical condition for which the DME is being prescribed.

CERTIFICATE OF MEDICAL NECESSITY (CMN)
Providers and suppliers no longer need to submit Certificate of Medical Necessity (CMN) for services rendered on or after January 1, 2023.

- For claims with dates of service on or after January 1, 2023 – Providers and suppliers no longer need to submit CMNs or DIFs with claims. Due to electronic filing requirements, claims received with these forms attached will be rejected and returned to the provider or supplier.
- For claims with dates of service prior to January 1, 2023 – If the CMN or DIF is required, it must be submitted with the claim, or be on file with a previous claim.

CODING GUIDELINES

1. An electrical osteogenesis stimulator is a device that provides electrical stimulation to promote bone repair. A noninvasive electrical stimulator is characterized by an external power source which is attached to a coil or electrodes placed on the skin or on a cast or brace over a fracture or fusion site.

2. An ultrasonic osteogenesis stimulator is a noninvasive device that emits low intensity, pulsed ultrasound. The ultrasound signal is applied to the skin surface at the fracture location via ultrasound conductive coupling gel in order to stimulate fracture healing.

Definitions

1. A multilevel spinal fusion is one which involves 3 or more vertebrae (e.g., L3-L5, L4-S1, etc).
2. A long bone is limited to a clavicle, humerus, radius, ulna, femur, tibia, fibula, metacarpal, or metatarsal.

Important Note:

Northwood's Medical Policies are developed to assist Northwood in administering plan benefits and determining whether a particular DMEPOS product or service is reasonable and necessary. Equipment that is used primarily and customarily for a non-medical purpose is not considered durable medical equipment.

Coverage determinations are made on a case-by-case basis and are subject to all of the terms, conditions, limitations, and exclusions of the member's contract including medical necessity requirements.

The conclusion that a DMEPOS product or service is reasonable and necessary does not constitute coverage. The member's contract defines which DMEPOS product or service is covered, excluded or limited. The policies provide for clearly written, reasonable and current criteria that have been approved by Northwood's Medical Director.

The clinical criteria and medical policies provide guidelines for determining the medical necessity for specific DMEPOS products or services. In all cases, final benefit determinations are based on the applicable contract language. To the extent there are any conflicts between medical policy guidelines and applicable contract language, the contract language prevails. Medical policy is not intended to override the policy that defines the member's benefits, nor is it intended to dictate to providers how to direct care. Northwood Medical policies shall not be interpreted to limit the benefits afforded to Medicare or Medicaid members by law and regulation and Northwood will use the applicable state requirements to determine required quantity limit guidelines.

Northwood's policies do not constitute medical advice. Northwood does not provide or recommend treatment to members. Members should consult with their treating practitioner in connection with diagnosis and treatment decisions.

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Northwood follows all CMS National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), as applicable.

References

Hayes, Inc. Ultrasound Bone Growth Stimulation. Medical Technology Directory. September 9, 2009.

Centers for Medicare and Medicaid Services, Medicare Coverage Database, National Coverage Documents; October 2015.

CGS Administrators, LLC. Jurisdiction B DME MAC, Osteogenesis Stimulators. Local Coverage Determination No. L33796; Last accessed/reviewed December 3, 2024.

Noridian Healthcare Solutions, LLC. Osteogenesis Stimulators. Local Coverage Determination No. L33796. Durable Medical Equipment Medicare Administrative Carrier Jurisdiction A; revised January 1, 2020. Reviewed December 12, 2018, December 2020. Accessed/reviewed December 06, 2021

Change/Authorization History

Revision Number	Date	Description of Change	Prepared/Reviewed by	Approved by	Review Date:	Effective Date:
A	Nov.2006	Initial Release	Rosanne Brugnoni	Ken Fasse	n/a	
01	June 2007	Eliminated requirement to report ICD-9 code 733.82 for non-unions. Added A4559 and Deleted E1399 See policy for details	Susan Glomb	Ken Fasse		
02		Annual Review / no changes	Susan Glomb	Ken Fasse	Dec.2008	
03	08-01-09	Policy updated to include: ultrasonic in statement regarding correct CMN to use for electrical osteogenesis stimulators.	Susan Glomb	Ken Fasse		
04	Dec. 4, 2009	Annual Review/ no changes	Susan Glomb	Ken Fasse	Dec. 4, 2009	

05	12-03-10	Annual Review – No changes	Susan Glomb	Ken Fasse	Dec.2010	
06	07-20-11	Added Important Note to all Medical Policies	Susan Glomb	Dr. B. Almasri		
07	11-16-11	Annual Review. Added References to Policy	Susan Glomb	Dr. B. Almasri	Nov. 2011	
08	05-29-12	Clarification of coverage/non-coverage criteria. Policy updated to include reasonable and necessary criteria for fresh fractures. Hayes reference added.	Susan Glomb	Dr. B. Almasri	May 2012	
09	12-04-12	Annual review – no changes.	Susan Glomb	Dr. B. Almasri	Dec. 2012	
10	12-18-13	Annual review. No changes.	Susan Glomb	Dr. B. Almasri		
11	11-25-14	Annual Review. Added: Items in this policy may be subject to the Affordable Care Act (ACA) 6407 requirements.	Susan Glomb	Dr. B. Almasri		
12	12-16-15	Annual Review. Updated policy with Medicare criteria. References updated.	Susan Glomb	Dr. B. Almasri		
13	12-06-16	Annual Review. No Changes.	Lisa Wojno	Dr. B. Almasri	December 2016	
14	12-20-17	Annual review. No changes.	Carol Dimech	Dr. C. Lerchin	December 2017	
15	12-12-18	Annual review. Medicare references updated.	Carol Dimech	Dr. C. Lerchin	December 2018	
16	12-04-19	Annual review. No changes.	Carol Dimech	Dr. C. Lerchin	December 2019	December 2019
17	12-04-20	Annual Review. Updated 'physician' to 'practitioner' as applicable.	Lisa Wojno	Dr. C. Lerchin	December 2020	December 2020

18	12-06-21	Annual Review. Added NCD/LCD verbiage to "Important Note".	Carol Dimech/Susan Glomb	Dr. C. Lerchin	December 06, 2021	
19	12-2-22	Annual review. Per CMS, added CMN update effective 1-1-23.	Carol Dimech	Dr. C. Lerchin	12-2-22	1-1-23
20	12-6-23	Annual review. No changes.	Carol Dimech	Dr. C. Lerchin	12-6-23	12-6-23
21	12-3-24	Annual review. No changes	Susan Glomb	Dr. C. Lerchin	12-3-24	12-3-24