

## Medical Policy



### 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

##### Medicare Member Coverage Criteria:

Refer to Medicare's medical policy (L33796) and article (A52513) for coverage criteria.

##### Non-Medicare Member Coverage Criteria:

Coverage Criteria:

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

**Nonspinal 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,

## Medical Policy



### Osteogenesis Stimulators – Spinal and Non-Spinal

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.

## Medical Policy



### Osteogenesis Stimulators – Spinal and Non-Spinal

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

#### 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 requirements.

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.

#### Definitions

# Medical Policy



## Osteogenesis Stimulators – Spinal and Non-Spinal

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.

### SPECIAL COVERAGE INFORMATION PER PLAN:

<p><b>SHP COMMERCIAL / SAS MEMBERS ONLY</b></p> <p><b>CLINICAL AUTHORIZATION CRITERIA:</b></p>	<p>A. Ultrasound Bone Growth Stimulator is considered medically necessary when <b>ONE</b> of the following criteria is met:</p> <ol style="list-style-type: none"><li>1. For treatment of closed fresh (acute) fracture of 5<sup>th</sup> metatarsal. A fracture is most commonly defined as fresh (acute) for 7 days after the fracture occurs. Fracture of the 5<sup>th</sup> metatarsal is difficult to heal because of poor vascular supply; or</li><li>2. Nonunion of fracture of 5<sup>th</sup> metatarsal when <b>ALL</b> of the following criteria are met:<ol style="list-style-type: none"><li>i. Fracture gap is &lt;1cm; and</li><li>ii. Nonunion is not related/secondary to malignancy; and</li><li>iii. It is greater than or equal to three months from the date of injury or initial treatment; and</li><li>iv. Fracture nonunion is documented by at least two sets of appropriate imaging studies separated by a minimum of 90 days confirming that clinically significant fracture healing has not occurred.</li></ol></li></ol> <p>B. Noninvasive electrical bone growth stimulator is considered medically necessary for a non-union of the 5<sup>th</sup></p>
--	--

# Medical Policy



## Osteogenesis Stimulators – Spinal and Non-Spinal

	<p>metatarsal fracture when ALL the following criteria <b>ARE</b> met:</p> <ol style="list-style-type: none"><li>1. The bone is non-infected; and</li><li>2. The two portions of the bone involved in the non-union are separated by less than 1 centimeter (cm); and</li><li>3. When serial radiographs (x-rays) have confirmed that fracture healing has ceased for three or more months prior to starting treatment with the electrical bone growth stimulator. Serial radiographs must include a minimum of two sets of radiographs, each including multiple views of the fracture site, separated by a minimum of 90 days.</li></ol>
<b>LIMITATIONS/EXCLUSIONS:</b>	<p>A. The following are non-covered services as they are considered experimental or investigational:</p> <ol style="list-style-type: none"><li>1. Ultrasonic osteogenic stimulators may not be used concurrently with other non-invasive osteogenic devices.</li></ol>

### 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.

# Medical Policy



## Osteogenesis Stimulators – Spinal and Non-Spinal

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

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.

### 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 6, 2023.

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 6, 2021

### Change/Authorization History

Revision	Date	Description of	Prepared/Reviewed		Review	Effective
----------	------	----------------	-------------------	--	--------	-----------

# Medical Policy



## Osteogenesis Stimulators – Spinal and Non-Spinal

Number		Change	by	Approved by	Date:	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	Susan Glomb	Dr. B. Almasri	May 2012	

## Medical Policy



### Osteogenesis Stimulators – Spinal and Non-Spinal

		include reasonable and necessary criteria for fresh fractures. Hayes reference added.				
09	12-4-12	Annual Review – No changes	Susan Glomb	Dr. B. Almasri	Dec 12	
10	12-18-13	Annual review. No changes	Susan Glomb	Dr. B. Almasri		
11	12-4-14	Annual Review. Added: Items in this policy may be subject to the Affordable Care Act (ACA) 6407 requirements.	Susan Glomb	Dr. B. Almasri		
12	12-7-15	Annual review. Removed reference to ICD 10 codes. Updated policy to more concise version of Medicare LCD and Medical Policy.	Susan Glomb	Dr. B. Almasri	12-7-15	
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	8-20-18	Special coverage information added for SHP Commercial/SAS member's only and found in "boxed" area on page 3	Susan Glomb	Dr. C. Lerchin		
16	12-12-18	Annual review. Medicare	Carol Dimech	Dr. C. Lerchin	December 2018	



## Medical Policy



### Osteogenesis Stimulators – Spinal and Non-Spinal

		references updated.				
17	12-04-19	Annual review. No changes.	Carol Dimech	Dr. C. Lerchin	December 2019	December 2019
18	12-04-20	Annual Review. Updated 'physician' to 'practitioner' as applicable.	Lisa Wojno	Dr. C. Lerchin	December 2020	December 2020
19	12-06-21	Annual review. Added NCD/LCD verbiage to "Important Note"	Carol Dimech/Susan Glomb	Dr. C. Lerchin	December 6, 2021	
20	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
21	12-6-23	Annual review. No changes.	Carol Dimech	Dr. C. Lerchin	December 6, 2023	December 6, 2023