

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

Coverage Criteria:

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

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, 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.

SHP COMMERCIAL / SAS MEMBERS ONLY

CLINICAL AUTHORIZATION CRITERIA:

- A. Ultrasound Bone Growth Stimulator is considered medically necessary when **ONE** of the following criteria is met:
1. For treatment of closed fresh (acute) fracture of 5th metatarsal. A fracture is most commonly defined as fresh (acute) for 7 days after the fracture occurs. Fracture of the 5th metatarsal is difficult to heal because of poor vascular supply; or
 2. Nonunion of fracture of 5th metatarsal when **ALL** of the following criteria are met:
 - i. Fracture gap is <1cm; and
 - ii. Nonunion is not related/secondary to malignancy; and
 - iii. It is greater than or equal to three months from the date of injury or initial treatment; and
 - 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.
- B. Noninvasive electrical bone growth stimulator is considered medically necessary for a non-union of the 5th metatarsal fracture when **ALL** the following criteria **ARE** met:
1. The bone is non-infected; and
 2. The two portions of the bone involved in the non-union are separated by less than 1 centimeter (cm); and
 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.

LIMITATIONS/EXCLUSIONS:

- A. The following are non-covered services as they are considered experimental or investigational:
1. Ultrasonic osteogenic stimulators may not be used concurrently with other non-invasive osteogenic devices.

▼ 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 physician 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.

▼ 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 physician 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; revised date October 1, 2015. Reviewed December 12, 2018.

Noridian Healthcare Solutions, LLC. Osteogenesis Stimulators. Local Coverage Determination No. L33796. Durable Medical Equipment Medicare Administrative Carrier Jurisdiction A; revised August 1, 2009. Reviewed December 12, 2018.

Applicable URAC Standard

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| Core 8 | Staff operational tools and support |
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Change/Authorization History

| Revision Number | Date | Description of Change | Prepared/ Reviewed by | Approved by | Review 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 | 12-4-12 | 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 |

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| 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 references updated. | Carol Dimech | Dr. C. Lerchin | December 2018 |