



# Local Coverage Determination (LCD) for Osteogenesis Stimulators (L11490)

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## Contractor Information

Contractor Name <a href="#">Noridian Administrative Services</a>	Contract Number 19003	Contract Type DME MAC
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## LCD Information

### Document Information

LCD Database ID Number  
L11490

LCD Title  
Osteogenesis Stimulators

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### Jurisdiction

Alaska  
American Samoa  
Arizona  
California - Entire State  
Northern Mariana Islands  
Guam  
Hawaii  
Iowa  
Idaho  
Kansas  
Missouri - Entire State  
Montana  
North Dakota  
Nebraska  
Nevada  
Oregon  
South Dakota  
Utah  
Washington  
Wyoming

DME Region LCD Covers  
Jurisdiction D

Original Effective Date  
For services performed on or after 10/01/1993

Revision Effective Date  
For services performed on or after 08/01/2009

Revision Ending Date  
N/A

Retirement Date  
N/A

Notice Period Start Date  
08/01/1993

Notice Period End Date  
N/A

## CMS National Coverage Policy

CMS Pub. 100-3, Medicare National Coverage Determination Manual, Chapter 1, Section 150.2

## Coverage Guidance

**Coverage Indications, Limitations and/or Medical Necessity**

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this local coverage determination, the criteria for "reasonable and necessary", based on Social Security Act §1862(a)(1)(A) provisions, are defined by the following indications and limitations of coverage and/or medical necessity.

For an item to be covered by Medicare, a detailed written order (DWO) must be received by the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving the completed DWO, the item will be denied as not reasonable and necessary.

A nonspinal electrical osteogenesis stimulator (E0747) is covered only if any of the following criteria are met:

1. Nonunion of a long bone fracture (ICD-9 codes - 810.00-810.13, 812.00-813.93, 815.00-815.19, 820.00-821.39, 823.00-824.9, 825.25, 825.35)(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 (ICD-9 code V45.4) where a minimum of nine months has elapsed since the last surgery, or
3. Congenital pseudarthrosis (ICD-9 code 755.8).

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 nonspinal electrical osteogenesis stimulator will be denied as not medically necessary if none of the criteria above are met.

A spinal electrical osteogenesis stimulator (E0748) is covered only if any of the following criteria are met:

1. Failed spinal fusion (ICD-9 code V45.4) where a minimum of nine months has elapsed since the last surgery, or
2. Following a multilevel spinal fusion surgery (ICD-9 code V45.4) (see Appendices section), or
3. Following spinal fusion surgery (ICD-9 code V45.4) where there is a history of a previously failed spinal fusion at the same site.

A spinal electrical osteogenesis stimulator will be denied as not medically necessary if none of the criteria above are met.

An ultrasonic osteogenesis stimulator (E0760) is covered only if all of the following criteria are met:

1. Nonunion of a fracture (ICD-9 codes - 807.00-807.3, 808.0-808.9, 810.00-816.13, 820.00-826.1) 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
2. The fracture is not of the skull or vertebrae; and
3. The fracture is not tumor related.

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

Use of an ultrasonic osteogenic stimulator for the treatment of a fresh fracture or delayed union will be denied as not medically 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 medically necessary if it is used with other noninvasive osteogenesis stimulators.

**REFILL REQUIREMENTS**

For DMEPOS items and supplies provided on a recurring basis, billing must be based on prospective, not retrospective use. For DMEPOS products that are supplied as refills to the original order, suppliers must contact the beneficiary prior to dispensing the refill and not automatically ship on a pre-determined basis, even if authorized by the beneficiary. This shall be done to ensure that the refilled item remains reasonable and necessary, existing supplies are approaching exhaustion, and to confirm any changes or modifications to the order. Contact with the beneficiary or designee regarding refills must take place no sooner than 14 calendar days prior to the delivery/shipping date. For delivery of refills, the supplier must deliver the DMEPOS product no sooner than 10 calendar days prior to the end of usage for the current product. This is regardless of which delivery method is utilized. (CMS Program Integrity Manual, Internet-Only Manual, CMS Pub. 100-8, Chapter 5, Section 5.2.6).

For all DMEPOS items that are provided on a recurring basis, suppliers are required to have contact with the beneficiary or caregiver/designee prior to dispensing a new supply of items. Suppliers must not deliver refills without a refill request from a beneficiary. Items delivered without a valid, documented refill request will be denied as not reasonable and necessary.

Suppliers must not dispense a quantity of supplies exceeding a beneficiary's expected utilization. Suppliers must stay attuned to changed or atypical utilization patterns on the part of their clients. Suppliers must verify with the ordering physicians that any changed or atypical utilization is warranted. Regardless of utilization, a supplier must not dispense more than a three (3)-month quantity at a time.

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**Coding Information****Bill Type Codes:**

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

## Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

## CPT/HCPCS Codes

Group 1 Paragraph: The appearance of a code in this section does not necessarily indicate coverage.

## HCPCS MODIFIERS:

EY - No physician or other licensed health care provider order for this item or service

KF – FDA Class III Device

## EQUIPMENT:

## Group 1 Codes:

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

## Group 2 Paragraph: SUPPLIES/OTHER:

## Group 2 Codes:

A4559	COUPLING GEL OR PASTE, FOR USE WITH ULTRASOUND DEVICE, PER OZ
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## ICD-9 Codes that Support Medical Necessity

Group 1 Paragraph: The presence of an ICD-9 code listed in this section is not sufficient by itself to assure coverage. Refer to the section on "Indications and Limitations of Coverage and/or Medical Necessity" for other coverage criteria and payment information.

For HCPCS code E0747:

## Group 1 Codes:

755.8	OTHER SPECIFIED CONGENITAL ANOMALIES OF UNSPECIFIED LIMB
810.00 - 810.13	CLOSED FRACTURE OF CLAVICLE UNSPECIFIED PART - OPEN FRACTURE OF ACROMIAL END OF CLAVICLE
812.00 - 813.93	FRACTURE OF UNSPECIFIED PART OF UPPER END OF HUMERUS CLOSED - FRACTURE OF UNSPECIFIED PART OF RADIUS WITH ULNA OPEN
815.00 - 815.19	CLOSED FRACTURE OF METACARPAL BONE(S) SITE UNSPECIFIED - OPEN FRACTURE OF MULTIPLE SITES OF METACARPUS
820.00 - 821.39	FRACTURE OF UNSPECIFIED INTRACAPSULAR SECTION OF NECK OF FEMUR CLOSED - OTHER FRACTURE OF LOWER END OF FEMUR OPEN
823.00 - 824.9	CLOSED FRACTURE OF UPPER END OF TIBIA - UNSPECIFIED FRACTURE OF ANKLE OPEN
825.25	FRACTURE OF METATARSAL BONE(S) CLOSED
825.35	FRACTURE OF METATARSAL BONE(S) OPEN
V45.4	POSTSURGICAL ARTHRODESIS STATUS

Group 1 Asterisk: N/A

Group 2 Paragraph: For HCPCS code E0748:

## Group 2 Codes:

V45.4	POSTSURGICAL ARTHRODESIS STATUS
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Group 2 Asterisk: N/A

Group 3 Paragraph: For HCPCS code E0760:

## Group 3 Codes:

807.00 - 807.3	CLOSED FRACTURE OF RIB(S) UNSPECIFIED - OPEN FRACTURE OF STERNUM
808.0 - 808.9	CLOSED FRACTURE OF ACETABULUM - UNSPECIFIED OPEN FRACTURE OF PELVIS
810.00 - 816.13	CLOSED FRACTURE OF CLAVICLE UNSPECIFIED PART - OPEN FRACTURE OF MULTIPLE SITES OF PHALANX OR PHALANGES OF HAND

820.00 - 826.1

FRACTURE OF UNSPECIFIED INTRACAPSULAR SECTION OF NECK OF FEMUR CLOSED - OPEN FRACTURE OF ONE OR MORE PHALANGES OF FOOT

Group 3 Asterisk: N/A

ICD-9 Codes that DO NOT Support Medical Necessity

All ICD-9 codes and diagnoses that are not specified in the preceding sections.

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## General Information

### Associated Information DOCUMENTATION REQUIREMENTS

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider." It is expected that the beneficiary's medical records will reflect the need for the care provided. The beneficiary's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available upon request.

### PRESCRIPTION (ORDER) REQUIREMENTS

#### GENERAL (PIM 5.2.1)

All items billed to Medicare require a prescription. An order for each item billed must be signed and dated by the treating physician, kept on file by the supplier, and made available upon request. Items dispensed and/or billed that do not meet these prescription requirements and those below must be submitted with an EY modifier added to each affected HCPCS code.

#### DISPENSING ORDERS (PIM 5.2.2)

Equipment and supplies may be delivered upon receipt of a dispensing order except for those items that require a written order prior to delivery. A dispensing order may be verbal or written. The supplier must keep a record of the dispensing order on file. It must contain:

- Description of the item
- Beneficiary's name
- Prescribing Physician's name
- Date of the order and the start date, if the start date is different from the date of the order
- Physician signature (if a written order) or supplier signature (if verbal order)

For the "Date of the order" described above, use the date the supplier is contacted by the physician (for verbal orders) or the date entered by the physician (for written dispensing orders).

Signature and date stamps are not allowed. Signatures must comply with the CMS signature requirements outlined in PIM 3.3.2.4.

The dispensing order must be available upon request.

For items that are provided based on a dispensing order, the supplier must obtain a detailed written order before submitting a claim.

#### DETAILED WRITTEN ORDERS (PIM 5.2.3)

A detailed written order (DWO) is required before billing. Someone other than the ordering physician may produce the DWO. However, the ordering physician must review the content and sign and date the document. It must contain:

- Beneficiary's name
- Physician's name
- Date of the order and the start date, if start date is different from the date of the order
- Detailed description of the item(s) (see below for specific requirements for selected items)
- Physician signature and signature date

For items provided on a periodic basis, including drugs, the written order must include:

- Item(s) to be dispensed
- Dosage or concentration, if applicable
- Route of Administration

- Frequency of use
- Duration of infusion, if applicable
- Quantity to be dispensed
- Number of refills

For the "Date of the order" described above, use the date the supplier is contacted by the physician (for verbal orders) or the date entered by the physician (for written dispensing orders).

Frequency of use information on orders must contain detailed instructions for use and specific amounts to be dispensed. Reimbursement shall be based on the specific utilization amount only. Orders that only state "PRN" or "as needed" utilization estimates for replacement frequency, use, or consumption are not acceptable. (PIM 5.9)

The detailed description in the written order may be either a narrative description or a brand name/model number.

Signature and date stamps are not allowed. Signatures must comply with the CMS signature requirements outlined in PIM 3.3.2.4.

The DWO must be available upon request.

A prescription is not considered as part of the medical record. Medical information intended to demonstrate compliance with coverage criteria may be included on the prescription but must be corroborated by information contained in the medical record.

#### MEDICAL RECORD INFORMATION

##### GENERAL (PIM 5.7 - 5.9)

The Indications and Limitations of Coverage and/or Medical Necessity section of this LCD contains numerous reasonable and necessary (R&N) requirements. The Nonmedical Necessity Coverage and Payment Rules section of the related Policy Article contains numerous non-reasonable and necessary, benefit category and statutory requirements that must be met in order for payment to be justified. Suppliers are reminded that:

- Supplier-produced records, even if signed by the ordering physician, and attestation letters (e.g. letters of medical necessity) are deemed not to be part of a medical record for Medicare payment purposes.
- Templates and forms, including CMS Certificates of Medical Necessity, are subject to corroboration with information in the medical record.

Information contained directly in the contemporaneous medical record is the source required to justify payment except as noted elsewhere for prescriptions and CMNs. The medical record is not limited to physician's office records but may include records from hospitals, nursing facilities, home health agencies, other healthcare professionals, etc. (not all-inclusive). Records from suppliers or healthcare professionals with a financial interest in the claim outcome are not considered sufficient by themselves for the purpose of determining that an item is reasonable and necessary.

##### CONTINUED USE

Continued use describes the ongoing utilization of supplies or a rental item by a beneficiary.

Suppliers are responsible for monitoring utilization of DMEPOS rental items and supplies. No monitoring of purchased items or capped rental items that have converted to a purchase is required. Suppliers must discontinue billing Medicare when rental items or ongoing supply items are no longer being used by the beneficiary.

Beneficiary medical records or supplier records may be used to confirm that a DMEPOS item continues to be used by the beneficiary. Any of the following may serve as documentation that an item submitted for reimbursement continues to be used by the beneficiary:

- Timely documentation in the beneficiary's medical record showing usage of the item, related option/accessories and supplies
- Supplier records documenting the request for refill/replacement of supplies in compliance with the Refill Documentation Requirements (This is deemed to be sufficient to document continued use for the base item, as well)
- Supplier records documenting beneficiary confirmation of continued use of a rental item

Timely documentation is defined as a record in the preceding 12 months unless otherwise specified elsewhere in this policy.

##### CONTINUED MEDICAL NEED

For all DMEPOS items, the initial justification for medical need is established at the time the item(s) is first ordered; therefore, beneficiary medical records demonstrating that the item is reasonable and necessary are created just prior to, or at the time of, the creation of the initial prescription. For purchased items, initial months of a rental item or for initial months of ongoing supplies or drugs, information justifying reimbursement will come from this initial time period. Entries in the beneficiary's medical record must have been created prior to, or at the time of, the initial DOS to establish whether the initial reimbursement was justified based upon the applicable coverage policy.

For ongoing supplies and rental DME items, in addition to information described above that justifies the initial provision of the item(s) and/or supplies, there must be information in the beneficiary's medical record to support that the item continues to be used by the beneficiary and remains reasonable and necessary. Information used to justify continued medical need must be timely for the DOS under review. Any of the following may serve as documentation justifying continued medical need:

- A recent order by the treating physician for refills
- A recent change in prescription
- A properly completed CMN or DIF with an appropriate length of need specified
- Timely documentation in the beneficiary's medical record showing usage of the item.

Timely documentation is defined as a record in the preceding 12 months unless otherwise specified elsewhere in the policy.

#### REFILL DOCUMENTATION (PIM 5.2.5-6)

A routine refill prescription is not needed. A new prescription is needed when:

- There is a change of supplier
- There is a change in the item(s), frequency of use, or amount prescribed
- There is a change in the length of need or a previously established length of need expires
- State law requires a prescription renewal

For items that the beneficiary obtains in-person at a retail store, the signed delivery slip or a copy of the itemized sales receipt is sufficient documentation of a request for refill.

For items that are delivered to the beneficiary, documentation of a request for refill must be either a written document received from the beneficiary or a contemporaneous written record of a phone conversation/contact between the supplier and beneficiary. The refill request must occur and be documented before shipment. A retrospective attestation statement by the supplier or beneficiary is not sufficient. The refill record must include:

- Beneficiary's name or authorized representative if different than the beneficiary
- A description of each item that is being requested
- Date of refill request
- Information documenting that the beneficiary's remaining supply is approaching exhaustion by the expected delivery date
- For consumable supplies, i.e., those that are used up (e.g., ostomy or urological supplies, surgical dressings, etc.) - the supplier should assess the quantity of each item that the beneficiary still has remaining, to document that the amount remaining will be nearly exhausted on or about the supply anniversary date.
- For non-consumable supplies, i.e., those more durable items that are not used up but may need periodic replacement (e.g., PAP and RAD supplies) - the supplier should assess whether the supplies remain functional, providing replacement (a refill) only when the supply item(s) is no longer able to function. Document the functional condition of the item(s) being refilled in sufficient detail to demonstrate the cause of the dysfunction that necessitates replacement (refill).

This information must be kept on file and be available upon request.

#### PROOF OF DELIVERY (PIM 4.26, 5.8)

Proof of delivery (POD) is a Supplier Standard and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) suppliers are required to maintain POD documentation in their files. For medical review purposes, POD serves to assist in determining correct coding and billing information for claims submitted for Medicare reimbursement. Regardless of the method of delivery, the contractor must be able to determine from delivery documentation that the supplier properly coded the item(s), that the item(s) delivered are the same item(s) submitted for Medicare reimbursement and that the item(s) are intended for, and received by, a specific Medicare beneficiary.

Suppliers, their employees, or anyone else having a financial interest in the delivery of the item are prohibited from signing and accepting an item on behalf of a beneficiary (i.e., acting as a designee on behalf of the beneficiary). The signature and date the beneficiary or designee accepted delivery must be legible.

For the purpose of the delivery methods noted below, designee is defined as any person who can sign and accept the delivery of DMEPOS on behalf of the beneficiary.

Proof of delivery documentation must be available to the Medicare contractor on request. All services that do not have appropriate proof of delivery from the supplier will be denied and overpayments will be requested. Suppliers who consistently fail to provide documentation to support their services may be referred to the OIG for imposition of Civil Monetary Penalties or other administrative sanctions.

Suppliers are required to maintain POD documentation in their files. There are two methods of delivery:

1. Delivery directly to the beneficiary or authorized representative
2. Delivery via shipping or delivery service

#### Method 1—Direct Delivery to the Beneficiary by the Supplier

Suppliers may deliver directly to the beneficiary or the designee. In this case, POD to a beneficiary must be a signed and dated delivery slip. The POD record must include:

- Beneficiary's name
- Delivery address
- Sufficiently detailed description to identify the item(s) being delivered (e.g., brand name, serial number, narrative description)
- Quantity delivered
- Date delivered
- Beneficiary (or designee) signature and date of signature

The date of signature on the delivery slip must be the date that the DMEPOS item was received by the beneficiary or designee. In instances where the item is delivered directly by the supplier, the date the beneficiary received the DMEPOS item must be the date of service on the claim.

#### Method 2—Delivery via Shipping or Delivery Service Directly to a Beneficiary

If the supplier utilizes a shipping service or mail order, the POD documentation must be a complete record tracking the item(s) from the DMEPOS supplier to the beneficiary. An example of acceptable proof of delivery would include both the supplier's own detailed shipping invoice and the delivery service's tracking information. The supplier's record must be linked to the delivery service record by some clear method like the delivery service's package identification number or supplier's invoice number for the package sent to the beneficiary. The POD record must include:

- Beneficiary's name
- Delivery address
- Delivery service's package identification number, supplier invoice number or alternative method that links the supplier's delivery documents with the delivery service's records.
- Sufficiently detailed description to identify the item(s) being delivered (e.g., brand name, serial number, narrative description)
- Quantity delivered
- Date delivered
- Evidence of delivery

If a supplier utilizes a shipping service or mail order, suppliers must use the shipping date as the date of service on the claim.

Suppliers may also utilize a return postage-paid delivery invoice from the beneficiary or designee as a POD. This type of POD record must contain the information specified above.

#### POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

For electrical and ultrasonic osteogenesis stimulators, a Certificate of Medical Necessity (CMN) which has been completed, signed, and dated by the treating physician must be kept on file by the supplier and made available upon request. The CMN may act as a substitute for a written order if it contains all of the required elements of an order. The CMN for both electrical and ultrasonic osteogenesis stimulators is CMS Form 847 (DME form 04.04C). The initial claim must include a copy of the CMN.

#### Appendices

A multilevel spinal fusion is one which involves 3 or more vertebrae (e.g., L3-L5, L4-S1, etc).

A long bone is limited to a clavicle, humerus, radius, ulna, femur, tibia, fibula, metacarpal, or metatarsal.

PIM citations above denote references to CMS Program Integrity Manual, Internet Only Manual 100-8

#### Utilization Guidelines

Refer to Indications and Limitations of Coverage and/or Medical Necessity.

#### Sources of Information and Basis for Decision

Reserved for future use.

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#### Revision History Information

**Please note:** The Revision History information included in this LCD prior to 1/24/2013 will now display with a Revision History Number of "R1" at the bottom of this table. All new Revision History information entries completed on or after 1/24/2013 will display as a row in the Revision History section of the LCD and numbering will begin with "R2".

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
08/01/2009	R2	Revision Effective Date: 08/01/2009 (March 2013 Publication) INDICATIONS AND LIMITATIONS OF COVERAGE: Revised: Order requirement language to specify a "detailed written order" Changed: Word "Patient" to "Beneficiary" Added: Refill requirements DOCUMENTATION REQUIREMENTS: Added: Standard Language (Note: The effective date above is not applicable to this section. These revised and added requirements are existing Medicare requirements which are now included in the LCD for easy reference) Revised: Prescription requirements	Provider Education/Guidance

08/01/2009	R1	<p>08/27/2011 - This policy was updated by the ICD-9 2011-2012 Annual Update.</p> <p>08/08/2009 - This policy was updated by the ICD-9 2009-2010 Annual Update.</p> <p>Revision Effective Date: 08/01/2009 DOCUMENTATION REQUIREMENTS: Included: Ultrasonic in statement regarding correct CMN to use for electrical osteogenesis stimulators.</p> <p>3/1/2008 - In accordance with Section 911 of the Medicare Modernization Act, this policy was transitioned to DME MAC Noridian Administrative Services (19003) LCD L11490 from DME PSC Electronic Data Systems Corp. (77006) LCD L11490.</p> <p>Revision Effective Date: 01/01/2007 INDICATIONS AND LIMITATIONS OF COVERAGE: Eliminated the requirement to report ICD-9 code 733.82 for nonunions HCPCS CODES AND MODIFIERS: Removed HCPCS Modifier KX Added: A4559 Deleted: E1399 ICD-9 CODES THAT SUPPORT MEDICAL NECESSITY: Eliminated 733.82 from the code set for E0747 and E0760. DOCUMENTATION REQUIREMENTS: CMN form revised - added new DME Form number and new requirement of completed CMN for ultrasonic osteogenesis stimulators Removed statement regarding using KX HCPCS Modifier when submitting claims for ultrasonic osteogenesis stimulator(s). Removed verbiage referring to HCPCS Code E1399 LCD ATTACHMENTS: Attached the new CMN</p> <p>03/01/2006 - In accordance with Section 911 of the Medicare Modernization Act of 2003, this policy was transitioned to DME PSC Electronic Data Systems Corp. (77006) from DMERC CIGNA Government Services (05655).</p> <p>Revision Effective Date: 04/27/2005 LMRP converted to LCD and Policy Article INDICATIONS AND LIMITATIONS OF COVERAGE AND OR MEDICAL NECESSITY: For ultrasonic stimulators, eliminated requirement for a failed surgical intervention HCPCS CODES AND MODIFIERS: Added KF modifier</p> <p>Revision Effective Date: 04/01/2003 HCPCS CODES AND MODIFIERS: Added: EY modifier to HCPCS Modifier array INDICATIONS AND LIMITATIONS OF COVERAGE: Added standard verbiage concerning coverage of items without an order. Added standard verbiage concerning the use of the EY modifier when no order is present for item on claim. CODING GUIDELINES: Moved definition of equipment here DOCUMENTATION REQUIREMENTS: Added standard language concerning use of the EY modifier for items without an order</p> <p>The revision dates listed below are the dates the revisions were published and not necessarily the effective dates for the revisions.</p>	Maintenance (annual review with new changes, formatting, etc.)
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07/01/2002 - Replaced ZX modifier with KX modifier.

04/01/2001 - The major changes are:

1. Ultrasonic osteogenesis stimulators (E0760) are covered under conditions specified in the recent revision to Medicare Coverage Issues Manual, Section 35-48.
2. Use a ZX modifier if coverage criteria for an ultrasonic osteogenesis stimulator are met. (The ZX modifier is not for use with electrical osteogenesis stimulators E0747 and E0748).
3. The Certificate of Medical Necessity (CMN) will not be used for ultrasonic osteogenesis stimulators, but will continue to be used for electrical osteogenesis stimulators.
4. Relevant ICD-9 diagnosis codes are required on claims for all osteogenesis stimulators, electrical and ultrasonic. For patients with nonunion of a fracture, in addition to the generic code for nonunion (733.82) the policy also requires the ICD-9 diagnosis code specifying the fracture site.

Coverage for ultrasonic osteogenesis stimulators became effective for claims with dates of service on or after January 1, 2001. The revised documentation requirements for all osteogenesis stimulators are effective for claims with dates of service on or after July 1, 2001.

The ultrasonic osteogenesis stimulator is in the Inexpensive or Routinely Purchased (IRP) payment category.

10/01/2000 - The description of a fracture nonunion is being clarified by indicating that the required radiographs must show no clinically significant healing. An article in the Spring 2000 DMERC Dialogue stated until the wording of question 6a on the Osteogenesis Stimulators CMN is revised to more clearly describe the new definition of a fracture nonunion, suppliers must attach a specific statement to each CMN that is sent to a physician. That statement is revised to say: "For purposes of answering question 6a on the attached Certificate of Medical Necessity (CMN), a fracture nonunion is considered to exist only when a minimum of two sets of radiographs obtained prior to starting treatment with the osteogenesis stimulator, separated by a minimum of 90 days and each including multiple views of the fracture site, have been interpreted by a physician in writing as showing that there has been no clinically significant evidence of fracture healing between the two sets of radiographs. If this definition of nonunion is not met, question 6a must be answered No."

04/01/2000 - The major change in the policy is a revision of the definition of nonunion of a long bone fracture which is one of the conditions for which a nonspinal electrical osteogenesis stimulator (E0747) is covered. This is the result of a change in the national policy in the Medicare Coverage Issues Manual 35-48. The revised policy is effective for claims with dates of service on or after April 1, 2000. The policy also clarifies the bones that are considered long bones.

Until such time as the wording of question 6a on the Osteogenesis Stimulators CMN (04.03C) can be revised to more clearly describe the new definition of a fracture nonunion, with each CMN that is sent to a physician the supplier must attach the following statement: "For purposes of answering question #6a on the attached Certificate of Medical Necessity (CMN), a fracture nonunion is considered to exist only when a

minimum of two sets of radiographs obtained prior to starting treatment with the osteogenesis stimulator, separated by a minimum of 90 days and each including multiple views of the fracture site, have been interpreted by a physician in writing as showing that there has been no evidence of fracture healing between the two sets of radiographs. If this definition of nonunion is not met, question 6a must be answered No."

06/01/1997 – Added HCPCS code E0760 including definition in Definition section. Coverage and Payment Rules section: Revised criteria 1 for nonspinal electrical osteogenesis stimulation to "after six or more months." Added "at the same site" to criteria 3 for spinal electrical osteogenesis stimulator. Added non-coverage language for E0760. Revised Documentation section.

04/01/1996 – Removed HCPCS code E0749, added code E0748. Revised Definition section. Incorporated Indications section into Coverage and Payment Rules section and expanded language regarding coverage criteria. Added Coding Guidelines section and revised Documentation section.

12/01/1993 – Corrected HAO to HA0 in Documentation section.

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## Associated Documents

### Attachments

[Certificate of Medical Necessity - Osteogenesis Stimulators \(42 KB\)](#)

### Related Local Coverage Documents

#### Article(s)

[A35423 - Osteogenesis Stimulators - Policy Article - Effective August 2009](#)

### Related National Coverage Documents

#### All Versions

[Updated on 03/10/2013 with effective dates 08/01/2009 - N/A](#)

[Updated on 03/08/2012 with effective dates 08/01/2009 - N/A](#)

[Updated on 10/07/2011 with effective dates 08/01/2009 - N/A](#)

[Updated on 09/29/2009 with effective dates 08/01/2009 - N/A](#)

[Updated on 07/26/2009 with effective dates 08/01/2009 - N/A](#)

[Updated on 02/19/2008 with effective dates 01/01/2007 - 07/31/2009](#)

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## Keywords

N/A

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## Local Coverage Article for Osteogenesis Stimulators - Policy Article - Effective August 2009 (A35423)

### Section Navigation

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### Contractor Information

Contractor Name <a href="#">Noridian Administrative Services</a>	Contractor Number 19003	Contractor Type DME MAC
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### Article Information

#### General Information

Article ID Number  
A35423

Article Type  
Article

Key Article  
Yes

Article Title  
Osteogenesis Stimulators - Policy Article - Effective August 2009

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#### Primary Geographic Jurisdiction

Alaska  
 American Samoa  
 Arizona  
 California - Entire State  
 Northern Mariana Islands  
 Guam  
 Hawaii  
 Iowa  
 Idaho  
 Kansas  
 Missouri - Entire State  
 Montana  
 North Dakota  
 Nebraska  
 Nevada  
 Oregon  
 South Dakota  
 Utah  
 Washington  
 Wyoming

DME Region Article Covers  
Jurisdiction D

Original Article Effective Date  
04/27/2005

Article Revision Effective Date  
08/01/2009

### Article Text

#### NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. "reasonable and necessary").

Osteogenesis stimulators are covered under the Durable Medical Equipment benefit (Social Security Act §1861(s)(6)). In order for a beneficiary's equipment to be

eligible for reimbursement, the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

The DME MAC does not process claims for an invasive osteogenesis stimulator.

#### CODING GUIDELINES

An electrical osteogenesis stimulator is a device that provides electrical stimulation to augment 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.

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.

Ultrasound conductive coupling gel is billed using code A4559.

E0747, E0748, and E0760, are class III devices which must be submitted with a KF modifier. Suppliers should contact the Pricing, Data Analysis and Coding (PDAC) Contractor for guidance on the correct coding of these items.

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#### Coding Information

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#### Other Information

Revision History Explanation  
Revision Effective Date: 08/01/2009 (March 2013 Publication)  
**NONMEDICAL NECESSITY COVERAGE AND PAYMENT RULES**  
Added: Preamble and benefit category statement

Revision Effective Date: 08/01/2009  
**CODING GUIDELINES:**  
Changed: SADMERC to PDAC

3/1/2008 - In accordance with Section 911 of the Medicare Modernization Act, this policy was transitioned to DME MAC Noridian Administrative Services (19003) Article A35423 from DME PSC Electronic Data Systems Corp. (77006) Article A35423.

Revision Effective Date: 01/01/2007  
**NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:**  
Removed DMERC reference; changed to DME MAC  
**CODING GUIDELINES:**  
Revised instructional statement regarding billing for ultrasound coupling gel to refer to new HCPCS code A4559.

03/01/2006 - In accordance with Section 911 of the Medicare Modernization Act of 2003, this article was transitioned to DME PSC Electronic Data Systems Corp. (77006) from DMERC CIGNA Government Services (05655).

Revision Effective Date: 04/27/2005  
LMRP converted to LCD and Policy Article  
**CODING GUIDELINES:**  
Added requirement for KF modifier for Class III Devices

Related Document(s)  
LCD(s)  
[L11490 - Osteogenesis Stimulators](#)

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#### All Versions

Updated on 03/10/2013 with effective dates 08/01/2009 - N/A  
Updated on 07/26/2009 with effective dates 08/01/2009 - N/A  
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