

LCD for Osteogenesis Stimulators (L11501)

Contractor Information

Contractor Name

[NHIC, Corp.](#)

Contractor Number

16003

Contractor Type

DME MAC

LCD Information

LCD ID Number

L11501

LCD Title

Osteogenesis Stimulators

Contractor's Determination Number

OSTG

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CMS National Coverage Policy

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

Primary Geographic Jurisdiction

Connecticut
District of Columbia
Delaware
Massachusetts
Maryland
Maine
New Hampshire
New Jersey
New York - Entire State
Pennsylvania
Rhode Island
Vermont

LCD Information

Oversight Region

Region I

DME Region LCD Covers

Jurisdiction A

Original Determination Effective Date

For services performed on or after 10/01/1993

Original Determination Ending Date

Revision Effective Date

For services performed on or after 08/01/2009

Revision Ending Date

Indications and Limitations of Coverage 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 medical policy, the criteria for "reasonable and necessary" are defined by the following indications and limitations of coverage and/or medical necessity.

For an item to be covered by Medicare, a written signed and dated order 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 order, the item will be denied as not medically 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).

LCD Information

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.

Coverage Topic

Durable Medical Equipment

Coding Information

CPT/HCPCS Codes

The appearance of a code in this section does not necessarily indicate coverage.

HCPCS MODIFIERS:

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

KF - FDA Class III Device

HCPCS CODES:

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/OTHER:

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

ICD-9 Codes that Support Medical Necessity

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:

755.8 OTHER SPECIFIED CONGENITAL ANOMALIES OF UNSPECIFIED LIMB

[810.00](#) - CLOSED FRACTURE OF CLAVICLE UNSPECIFIED PART - OPEN FRACTURE OF ACROMIAL END OF CLAVICLE
[810.13](#)

[812.00](#) - FRACTURE OF UNSPECIFIED PART OF UPPER END OF HUMERUS CLOSED -
[813.93](#) FRACTURE OF UNSPECIFIED PART OF RADIUS WITH ULNA OPEN

[815.00](#) - CLOSED FRACTURE OF METACARPAL BONE(S) SITE UNSPECIFIED - OPEN
[815.19](#) FRACTURE OF MULTIPLE SITES OF METACARPUS

[820.00](#) - FRACTURE OF UNSPECIFIED INTRACAPSULAR SECTION OF NECK OF FEMUR
[821.39](#) CLOSED - OTHER FRACTURE OF LOWER END OF FEMUR OPEN

[823.00](#) - CLOSED FRACTURE OF UPPER END OF TIBIA - UNSPECIFIED FRACTURE OF ANKLE
[824.9](#) OPEN

825.25 FRACTURE OF METATARSAL BONE(S) CLOSED

825.35 FRACTURE OF METATARSAL BONE(S) OPEN

V45.4 POSTSURGICAL ARTHRODESIS STATUS

For HCPCS code E0748:

V45.4 POSTSURGICAL ARTHRODESIS STATUS

Coding Information

For HCPCS code E0760:

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

Diagnoses that Support Medical Necessity

Refer to the previous section.

ICD-9 Codes that DO NOT Support Medical Necessity

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

ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation

Diagnoses that DO NOT Support Medical Necessity

All diagnoses that are not specified in the preceding section.

General 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 patient's medical records will reflect the need for the care provided. The patient'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.

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 billed before a signed and dated order has been received by the supplier must be submitted with an EY modifier added to each affected HCPCS code.

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.

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.

General Information

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.

Utilization Guidelines

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

Sources of Information and Basis for Decision

Reserved for future use.

Advisory Committee Meeting Notes

Start Date of Comment Period

04/16/1993

End Date of Comment Period

05/31/1993

Start Date of Notice Period

08/01/1993

Revision History Number

OSTG010

Revision History Explanation

Revision Effective Date: 08/01/2009

DOCUMENTATION REQUIREMENTS:

Included: Ultrasonic in statement regarding correct CMN to use for electrical osteogenesis stimulators.

03/01/2008 - In accordance with Section 911 of the Medicare Modernization Act, this policy was transitioned to DME MAC NHIC (16003) LCD L11501 from DME PSC TriCenturion (77011) LCD L11501.

06/01/2007 - In accordance with Section 911 of the Medicare Modernization Act of 2003, Virginia and West Virginia were transitioned from DME PSC TriCenturion (77011) to DME PSC TrustSolutions (77012).

Revision Effective Date: 01/01/2007

INDICATIONS AND LIMITATIONS OF COVERAGE: Eliminated the requirement to report ICD-9 code 733.82 for nonunions.

General Information

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:

Revised: CMN form.

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).

LCD ATTACHMENTS:

Attached: New CMN.

03/01/2006 - In accordance with Section 911 of the Medicare Modernization Act of 2003, this policy was transitioned to DME PSC TriCenturion (77011) from DMERC Tricenturion (77011).

Revision Effective Date: 04/27/2005

LMRP converted to LCD and Policy Article.

INDICATIONS AND LIMITATIONS OF COVERAGE AND OR MEDICAL NECESSITY:

Eliminated: Requirement for a failed surgical intervention for ultrasonic stimulators.

HCPCS CODES & MODIFIERS:

Added: KF modifier.

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.

The revision dates listed below are the dates the revisions were published and not necessarily the effective dates for the revisions.

07/01/2002 - Replaced ZX modifier with KX modifier.

4/01/2001 - 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.

General Information

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 HAO in Documentation section.

Reason for Change

Last Reviewed On Date

General Information

Related Documents

Article(s)

[A35349 - Osteogenesis Stimulators - Policy Article - Effective August 2009](#)

LCD Attachments

[OSTEO CMN CMS-847](#) (247,390 bytes)

Article for Osteogenesis Stimulators - Policy Article - Effective August 2009 (A35349)

Contractor Information

Contractor Name

[NHIC, Corp.](#)

Contractor Number

16003

Contractor Type

DME MAC

Article Information

Article ID Number

A35349

Article Type

Article

Key Article

Yes

Article Title

Osteogenesis Stimulators - Policy Article - Effective August 2009

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Primary Geographic Jurisdiction

Connecticut
District of Columbia
Delaware
Massachusetts
Maryland
Maine
New Hampshire
New Jersey
New York - Entire State
Pennsylvania
Rhode Island
Vermont

Article Information

DME Region Article Covers

Jurisdiction A

Original Article Effective Date

10/01/2005

Article Revision Effective Date

08/01/2009

Article Text

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES

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.

Coverage Topic

Durable Medical Equipment

Coding Information

No Coding Information has been entered in this section of the article.

Other Information

Revision History Explanation

Revision Effective Date: 08/01/2009

CODING GUIDELINES:

Changed: SADMERC to PDAC.

03/01/2008 - In accordance with Section 911 of the Medicare Modernization Act, this policy was transitioned to DME MAC NHIC (16003) Article A35349 from DME PSC TriCenturion (77011) Article A35349.

Other Information

06/01/2007 - In accordance with Section 911 of the Medicare Modernization Act of 2003, Virginia and West Virginia were transitioned from DME PSC TriCenturion (77011) to DME PSC TrustSolutions (77012).

Revision Effective Date: 01/01/2007

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

Removed: DMERC reference.

Changed: DMERC 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 TriCenturion (77011) from DMERC Tricenturion (77011).

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 Documents

LCD(s)

[L11501 - Osteogenesis Stimulators](#)