Local Coverage Determination (LCD): Osteogenesis Stimulators (L33796)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

## Contractor Information

<table>
<thead>
<tr>
<th>CONTRACTOR NAME</th>
<th>CONTRACT TYPE</th>
<th>CONTRACT NUMBER</th>
<th>JURISDICTION</th>
<th>STATE(S)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CGS Administrators, LLC</td>
<td>DME MAC</td>
<td>17013 - DME MAC</td>
<td>J-B</td>
<td>Illinois, Indiana, Kentucky, Michigan, Minnesota, Ohio, Wisconsin</td>
</tr>
<tr>
<td>CGS Administrators, LLC</td>
<td>DME MAC</td>
<td>18003 - DME MAC</td>
<td>J-C</td>
<td>Alabama, Arkansas, Colorado, Florida, Georgia, Louisiana, Mississippi,</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>New Mexico, North Carolina, Oklahoma, Puerto Rico, South Carolina,</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Tennessee, Texas, Virgin Islands, Virginia, West Virginia</td>
</tr>
<tr>
<td>CONTRACTOR NAME</td>
<td>CONTRACT TYPE</td>
<td>CONTRACT NUMBER</td>
<td>JURISDICTION</td>
<td>STATE(S)</td>
</tr>
<tr>
<td>---------------------------------</td>
<td>--------------</td>
<td>--------------------</td>
<td>--------------------------</td>
<td>---------------------------------</td>
</tr>
<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>DME MAC</td>
<td>19003 - DME MAC</td>
<td>J-D</td>
<td>Alaska</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>American Samoa</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Arizona</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>California - Entire State</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Guam</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Hawaii</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Idaho</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Iowa</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Kansas</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Missouri - Entire State</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Montana</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Nebraska</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Nevada</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>North Dakota</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Northern Mariana Islands</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Oregon</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>South Dakota</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Utah</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Washington</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Wyoming</td>
</tr>
</tbody>
</table>

**LCD Information**

**Document Information**

**LCD ID**

L33796

**Original ICD-9 LCD ID**

L11501
L5012
L27026
L11490

**LCD Title**

Osteogenesis Stimulators

**Original Effective Date**

For services performed on or after 10/01/2015

**Revision Effective Date**

For services performed on or after 01/01/2020

**Revision Ending Date**

N/A

**Retirement Date**

N/A

**Proposed LCD in Comment Period**

N/A

**Source Proposed LCD**

N/A

**Notice Period Start Date**

N/A

**Notice Period End Date**

N/A
CMS National Coverage Policy

CMS Pub. 100-03 (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.

The purpose of a Local Coverage Determination (LCD) is to provide information regarding “reasonable and necessary” criteria based on Social Security Act § 1862(a)(1)(A) provisions.
In addition to the "reasonable and necessary" criteria contained in this LCD there are other payment rules, which are discussed in the following documents, that must also be met prior to Medicare reimbursement:

- The LCD-related Standard Documentation Requirements Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- The LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- Refer to the Supplier Manual for additional information on documentation requirements.
- Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

For the items addressed in this LCD, the "reasonable and necessary" criteria, based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

A non-spinal electrical osteogenesis stimulator (E0747) is covered 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.

A non-spinal 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 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 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 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 radiograph set must include multiple views of the fracture site accompanied by a written interpretation by a treating practitioner 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 osteogenesis 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.

GENERAL

A Standard Written Order (SWO) must be communicated to the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving a completed SWO, the claim shall be denied as not reasonable and necessary.

For Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) base items that require a Written Order Prior to Delivery (WOPD), the supplier must have received a signed SWO before the DMEPOS item is delivered to a beneficiary. If a supplier delivers a DMEPOS item without first receiving a WOPD, the claim shall be denied as not reasonable and necessary. Refer to the LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.

For DMEPOS base items that require a WOPD, and also require separately billed associated options, accessories, and/or supplies, the supplier must have received a WOPD which lists the base item and which may list all the associated options, accessories, and/or supplies that are separately billed prior to the delivery of the items. In this scenario, if the supplier separately bills for associated options, accessories, and/or supplies without first receiving a completed and signed WOPD of the base item prior to delivery, the claim(s) shall be denied as not reasonable and necessary.

An item/service is correctly coded when it meets all the coding guidelines listed in CMS HCPCS guidelines, LCDs, LCD-related Policy Articles, or DME MAC articles. Claims that do not meet coding guidelines shall be denied as not reasonable and necessary/incorrectly coded.

Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD documentation in their files. Proof of delivery documentation must be made available to the Medicare contractor upon request. All services that do not have appropriate proof of delivery from the supplier shall be denied as not reasonable and necessary.

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.

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 treating practitioners 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.

Summary of Evidence

NA

Analysis of Evidence
(Rationale for Determination)

NA

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.

N/A

**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.

N/A

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 health care provider order for this item or service

KF - FDA Class III Device

HCPCS CODES:

EQUIPMENT:

Group 1 Codes:

<table>
<thead>
<tr>
<th>CODE</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>E0747</td>
<td>OSTEOGENESIS STIMULATOR, ELECTRICAL, NON-INVASIVE, OTHER THAN SPINAL APPLICATIONS</td>
</tr>
<tr>
<td>E0748</td>
<td>OSTEOGENESIS STIMULATOR, ELECTRICAL, NON-INVASIVE, SPINAL APPLICATIONS</td>
</tr>
<tr>
<td>E0760</td>
<td>OSTEOGENESIS STIMULATOR, LOW INTENSITY ULTRASOUND, NON-INVASIVE</td>
</tr>
</tbody>
</table>

Group 2 Paragraph:

SUPPLIES/OTHER:

Group 2 Codes:

<table>
<thead>
<tr>
<th>CODE</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>A4559</td>
<td>COUPLING GEL OR PASTE, FOR USE WITH ULTRASOUND DEVICE, PER OZ</td>
</tr>
</tbody>
</table>

ICD-10 Codes that Support Medical Necessity

Group 1 Paragraph:

Not applicable
GENERAL DOCUMENTATION REQUIREMENTS

In order to justify payment for DMEPOS items, suppliers must meet the following requirements:

- SWO
- Medical Record Information (including continued need/use if applicable)
- Correct Coding
- Proof of Delivery

Refer to the LCD-related Standard Documentation Requirements article, located at the bottom of this policy under the Related Local Coverage Documents section for additional information regarding these requirements.

Refer to the Supplier Manual for additional information on documentation requirements.

Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.
POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

Items covered in this LCD have additional policy-specific requirements that must be met prior to Medicare reimbursement.

Refer to the LCD-related Policy article, located at the bottom of this policy under the Related Local Coverage Documents section for additional information.

MISCELLANEOUS

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 Coverage Indications, Limitations and/or Medical Necessity

Sources of Information

N/A

Bibliography

NA

Revision History Information

<table>
<thead>
<tr>
<th>REVISION HISTORY DATE</th>
<th>REVISION HISTORY NUMBER</th>
<th>REVISION HISTORY EXPLANATION</th>
<th>REASON(S) FOR CHANGE</th>
</tr>
</thead>
</table>
| 01/01/2020            | R5                      | Revision Effective Date: 01/01/2020  
COVERAGE INDICATIONS, LIMITATIONS, AND/OR MEDICAL NECESSITY:  
Revised: “physician” to “treating practitioner”  
GENERAL: | • Provider Education/Guidance |
<table>
<thead>
<tr>
<th>REVISION HISTORY DATE</th>
<th>REVISION HISTORY NUMBER</th>
<th>REVISION HISTORY EXPLANATION</th>
<th>REASON(S) FOR CHANGE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Revised: Order information as a result of Final Rule 1713</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>REFILL REQUIREMENTS:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Revised: “ordering physicians” to “treating practitioners”</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>HCPCS MODIFIERS:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Revised: Typographical error for definition of EY modifier “sevice” to “service”</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>DOCUMENTATION REQUIREMENTS:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Revised: “physician’s” to “treating practitioner’s”</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>GENERAL DOCUMENTATION REQUIREMENTS:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Revised: “Prescriptions (orders)” to “SWO”</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>02/13/2020: Pursuant to the 21st Century Cures Act, these revisions do not require notice and comment because they are due to non-discretionary coverage updates reflective of CMS FR-1713.</td>
<td></td>
</tr>
<tr>
<td>01/01/2017</td>
<td>R4</td>
<td><strong>Revision Effective Date: 01/01/2017</strong></td>
<td>Provider Education/Guidance</td>
</tr>
<tr>
<td></td>
<td></td>
<td>COVERAGE INDICATIONS, INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Removed: Standard Documentation Language</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Added: New reference language and directions to Standard Documentation Requirements</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Added: General Requirements</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Revised: Refill Requirements</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>DOCUMENTATION REQUIREMENTS:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Removed: Standard Documentation Language</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Added: General Documentation Requirements</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Added: New reference language and directions to Standard Documentation Requirements</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>POLICY SPECIFIC DOCUMENTATION REQUIREMENTS:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Removed: Standard Documentation Language</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Added: Direction to Standard Documentation Requirements</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Removed: Supplier Manual reference from Miscellaneous section</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Removed: PIM reference under Appendices section</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>RELATED LOCAL COVERAGE DOCUMENTS:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Added: LCD-related Standard Documentation Requirements article</td>
<td></td>
</tr>
<tr>
<td>07/01/2016</td>
<td>R3</td>
<td>Effective July 1, 2016 oversight for DME MAC LCDs is the responsibility of CGS Administrators, LLC 18003</td>
<td>Change in Assigned</td>
</tr>
<tr>
<td>Revision History Date</td>
<td>Revision History Number</td>
<td>Revision History Explanation</td>
<td>Reason(s) for Change</td>
</tr>
<tr>
<td>-----------------------</td>
<td>-------------------------</td>
<td>------------------------------</td>
<td>----------------------</td>
</tr>
</tbody>
</table>
| 10/01/2015            | R2                      | Revision Effective Date: 10/01/2015  
**COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY:**  
Removed: References to ICD-10 Codes  
**ICD-10 CODES THAT SUPPORT MEDICAL NECESSITY:**  
Deleted: ICD-10 Codes | States or Affiliated Contract Numbers  
- Provider Education/Guidance  
- Revisions Due To ICD-10-CM Code Changes |
| 10/01/2015            | R1                      | Revision Effective Date: 10/31/2014  
**COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY:**  
Revised: Standard Documentation Language to add covered prior to a beneficiary’s Medicare eligibility  
**DOCUMENTATION REQUIREMENTS:**  
Revised: Standard Documentation Language to add who can enter date of delivery date on the POD  
**Added:** Instructions for Equipment Retained from a Prior Payer  
**Added:** Repair/Replacement section | Provider Education/Guidance |

### Associated Documents

**Attachments**

CMS-847-Osteogenesis Stimulators  
(PDF - 179 KB)

**Related Local Coverage Documents**

Article(s)

- A52513 - Osteogenesis Stimulators - Policy Article  
- A55426 - Standard Documentation Requirements for All Claims Submitted to DME MACs

**Related National Coverage Documents**

N/A

**Public Version(s)**

Updated on 02/07/2020 with effective dates 01/01/2020 - N/A  
Updated on 05/04/2017 with effective dates 01/01/2017 - 12/31/2019  
Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.
Keywords

N/A
END OF LOCAL COVERAGE DETERMINATION
Per the Code of Federal Regulations, 42 C.F.R § 426. 325, only those portions of the currently effective Local Coverage Determination (LCD) that are based on section 1862(a)(1)(A) of the Social Security Act, may be challenged through an acceptable complaint as described in 42 C.F.R § 426.400. Also, per 42 C.F.R § 426.325 items that are not reviewable, and therefore cannot be challenged, include the Policy Article. Please note the distinction of the documents when reviewing the materials.
## Contractor Information

<table>
<thead>
<tr>
<th>CONTRACTOR NAME</th>
<th>CONTRACT TYPE</th>
<th>CONTRACT NUMBER</th>
<th>JURISDICTION</th>
<th>STATE(S)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CGS Administrators, LLC</td>
<td>DME MAC</td>
<td>17013 - DME MAC</td>
<td>J-B</td>
<td>Illinois&lt;br&gt;Indiana&lt;br&gt;Kentucky&lt;br&gt;Michigan&lt;br&gt;Minnesota&lt;br&gt;Ohio&lt;br&gt;Wisconsin</td>
</tr>
<tr>
<td>CGS Administrators, LLC</td>
<td>DME MAC</td>
<td>18003 - DME MAC</td>
<td>J-C</td>
<td>Alabama&lt;br&gt;Arkansas&lt;br&gt;Colorado&lt;br&gt;Florida&lt;br&gt;Georgia&lt;br&gt;Louisiana&lt;br&gt;Mississippi&lt;br&gt;New Mexico&lt;br&gt;North Carolina&lt;br&gt;Oklahoma&lt;br&gt;Puerto Rico&lt;br&gt;South Carolina&lt;br&gt;Tennessee&lt;br&gt;Texas&lt;br&gt;Virgin Islands&lt;br&gt;Virginia&lt;br&gt;West Virginia</td>
</tr>
<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>DME MAC</td>
<td>16013 - DME MAC</td>
<td>J-A</td>
<td>Connecticut&lt;br&gt;Delaware&lt;br&gt;District of Columbia&lt;br&gt;Maine&lt;br&gt;Maryland&lt;br&gt;Massachusetts&lt;br&gt;New Hampshire&lt;br&gt;New Jersey&lt;br&gt;New York - Entire State&lt;br&gt;Pennsylvania&lt;br&gt;Rhode Island&lt;br&gt;Vermont</td>
</tr>
</tbody>
</table>
Article Information

General Information

Article ID
A52513

Original ICD-9 Article ID
A35349
A25956
A47113
A35423

Original Effective Date
10/01/2015

Revision Effective Date
01/01/2020

Revision Ending Date
N/A

Article Title
Osteogenesis Stimulators - Policy Article

Article Type
Article

AMC CPT / ADA CDT / AHA NUBC Copyright Statement
N/A
Article Guidance

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.

REQUIREMENTS FOR SPECIFIC DMEPOS ITEMS PURSUANT TO Final Rule 1713 (84 Fed. Reg Vol 217)

Final Rule 1713 (84 Fed. Reg Vol 217) requires a face-to-face encounter and a Written Order Prior to Delivery (WOPD) for specified HCPCS codes. CMS and the DME MACs provide a list of the specified codes, which is periodically updated. The link will be located here once it is available.

Claims for the specified items subject to Final Rule 1713 (84 Fed. Reg Vol 217) that do not meet the face-to-face encounter and WOPD requirements specified in the LCD-related Standard Documentation Requirements Article (A55426) will be denied as not reasonable and necessary.

If a supplier delivers an item prior to receipt of a WOPD, it will be denied as not reasonable and necessary. If the WOPD is not obtained prior to delivery, payment will not be made for that item even if a WOPD is subsequently obtained by the supplier. If a similar item is subsequently provided by an unrelated supplier who has obtained a WOPD, it will be eligible for coverage.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

In addition to policy specific documentation requirements, there are general documentation requirements that are applicable to all DMEPOS policies. These general requirements are located in the DOCUMENTATION REQUIREMENTS section of the LCD.

Refer to the LCD-related Standard Documentation Requirements article, located at the bottom of this Policy Article under the Related Local Coverage Documents section for additional information regarding GENERAL DOCUMENTATION REQUIREMENTS and the POLICY SPECIFIC DOCUMENTATION REQUIREMENTS discussed below.

CERTIFICATE OF MEDICAL NECESSITY (CMN)

A Certificate of Medical Necessity (CMN), which has been completed, signed, and dated by the treating practitioner, must be kept on file by the supplier and made available upon request. The CMN may act as a substitute for the Standard Written Order (SWO) if it contains the same information as required in a SWO. The CMN for both electrical and ultrasonic osteogenesis stimulators is CMS Form 847. In addition to the order information that the treating practitioner enters in Section B, the supplier can use the space in Section C for a written confirmation of other details of the order or the treating practitioner can enter the other details directly.

A new CMN is not required just because the supplier changes assignment status on the submitted claim.

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.

---

**Coding Information**

<table>
<thead>
<tr>
<th>CPT/HCPCS Codes</th>
<th>N/A</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>ICD-10 Codes that Support Medical Necessity</th>
<th>N/A</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>ICD-10 Codes that DO NOT Support Medical Necessity</th>
<th>N/A</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Additional ICD-10 Information</th>
<th>N/A</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Bill Type Codes:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Acceptance 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.</td>
</tr>
<tr>
<td>N/A</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Revenue Codes:</th>
</tr>
</thead>
<tbody>
<tr>
<td>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</td>
</tr>
<tr>
<td>N/A</td>
</tr>
</tbody>
</table>
Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

**Revision History Information**

<table>
<thead>
<tr>
<th>REVISION HISTORY DATE</th>
<th>REVISION HISTORY NUMBER</th>
<th>REVISION HISTORY EXPLANATION</th>
</tr>
</thead>
</table>
| 01/01/2020            | R5                      | **Revision Effective Date: 01/01/2020**  
NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:  
Removed: REQUIREMENTS FOR SPECIFIC DMEPOS ITEMS PURSUANT TO 42 CFR 410.38(g) section  
Added: REQUIREMENTS FOR SPECIFIC DMEPOS ITEMS PURSUANT TO FINAL RULE 1713 (84 Fed. Reg Vol 217) section and related information  
CERTIFICATE OF MEDICAL NECESSITY (CMN):  
Revised: “physician” to “treating practitioner”  
Removed: CMN form version number “(DME form 04.04C)”  
Revised: “detailed written order” to “SWO”  
ICD-10 CODES THAT SUPPORT MEDICAL NECESSITY:  
Revised: Section header “ICD-10 Codes that are Covered” updated to “ICD-10 Codes that Support Medical Necessity”  
ICD-10 CODES THAT DO NOT SUPPORT MEDICAL NECESSITY:  
Revised: Section header “ICD-10 Codes that are Not Covered” updated to “ICD-10 Codes that DO NOT Support Medical Necessity”  

02/13/2020: *At this time 21st Century Cures Act applies to new and revised LCDs which require comment and notice. This revision is to an article that is not a local coverage determination.*

| 01/01/2017            | R4                      | **Revision Effective Date: 01/01/2017**  
CODING INFORMATION:  
Removed: Bill type which was inadvertently added  

02/07/2019: *At this time 21st Century Cures Act applies to new and revised LCDs which require comment and notice. This revision is to an article and not a local coverage determination.*

| 01/01/2017            | R3                      | **Revision Effective Date: 01/01/2017**  
NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:  
Added: 42 CFR 410.38(g)  
POLICY SPECIFIC DOCUMENTATION REQUIREMENTS:
# Associated Documents

## Related Local Coverage Document(s)

**Article(s)**

- A55426 - Standard Documentation Requirements for All Claims Submitted to DME MACs

**LCD(s)**

- L33796 - Osteogenesis Stimulators

## Related National Coverage Document(s)

N/A

## Statutory Requirements URL(s)

N/A

## Rules and Regulations URL(s)

N/A

## CMS Manual Explanations URL(s)

N/A

## Other URL(s)

N/A

## Public Version(s)

- Updated on 02/07/2020 with effective dates 01/01/2020 - N/A
- Updated on 01/31/2019 with effective dates 01/01/2017 - N/A
- Updated on 05/04/2017 with effective dates 01/01/2017 - N/A

Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.

## Keywords

N/A