Local Coverage Determination (LCD) for Cervical Traction Devices (L15300)

Contractor Information

Contractor Name: Noridian Administrative Services
Contract Number: 19003
Contract Type: DME MAC

LCD Information

LCD Database ID Number: L15300

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 07/01/2004

Revision Effective Date
For services performed on or after 02/04/2011

Revision Ending Date
N/A

Retirement Date
N/A

Notice Period Start Date
03/01/2004

Notice Period End Date
N/A

CMS National Coverage Policy

CMS Manual System, Pub. 100-3, Medicare National Coverage Determinations Manual, Chapter 1, Section 280.1

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.

Cervical traction devices (E0840-E0855 and E0860) are covered only if both of the following criteria are met:
1. The beneficiary has a musculoskeletal or neurologic impairment requiring traction equipment; and
2. The appropriate use of a home cervical traction device has been demonstrated to the beneficiary and the beneficiary tolerated the selected device.

If criteria 1 and 2 are not met, cervical traction will be denied as not reasonable and necessary.

Cervical traction applied via attachment to a headboard (E0840) or a free-standing frame (E0850) has no proven clinical advantage compared to cervical traction applied via an over-the-door mechanism (E0860). If an E0840 or E0850 is ordered, it will be denied as not reasonable and necessary.

Cervical traction devices described by code E0849 or E0855 are covered only when criteria 1 and 2 above and either criterion A, B or C below has been met:
A. The beneficiary has a diagnosis of temporomandibular joint (TMJ) dysfunction; and has received treatment for the TMJ condition; or,
B. The beneficiary has distortion of the lower jaw or neck anatomy (e.g., radical neck dissection) such that a chin halter is unable to be utilized; or,
C. The treating physician orders and/or documents the medical necessity for greater than 20 pounds of cervical traction in the home setting.

If the criteria for cervical traction are met but the additional criteria for E0849 or E0855 are not met, they will be denied as not reasonable and necessary.

E0856 describes a cervical traction device that can be used with ambulation. Therefore, it will be denied as not reasonable and necessary.

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 health care provider order for this item or service
GA – Waiver of liability statement issued as required by payer policy, individual case
GZ – Item or service expected to be denied as not reasonable and necessary
KX - Requirements specified in the medical policy have been met

HCPCS CODES:

<table>
<thead>
<tr>
<th>Group 1 Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E0840</td>
<td>TRACTION FRAME, ATTACHED TO HEADBOARD, CERVICAL TRACTION</td>
</tr>
<tr>
<td>E0849</td>
<td>TRACTION EQUIPMENT, CERVICAL, FREE-STANDING STAND/FRAME, PNEUMATIC, APPLYING TRACTION FORCE TO OTHER THAN MANDIBLE</td>
</tr>
<tr>
<td>E0850</td>
<td>TRACTION STAND, FREE STANDING, CERVICAL TRACTION</td>
</tr>
<tr>
<td>E0855</td>
<td>CERVICAL TRACTION EQUIPMENT NOT REQUIRING ADDITIONAL STAND OR FRAME</td>
</tr>
<tr>
<td>E0856</td>
<td>CERVICAL TRACTION DEVICE, CERVICAL COLLAR WITH INFLATABLE AIR BLADDER</td>
</tr>
<tr>
<td>E0860</td>
<td>TRACTION EQUIPMENT, OVERDOOR, CERVICAL</td>
</tr>
</tbody>
</table>

ICD-9 Codes that Support Medical Necessity
Group 1 Paragraph: Not specified.
ICD-9 Codes that DO NOT Support Medical Necessity

Not specified.

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 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 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. For Cervical Traction Devices, there are two (2) 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**

An order for the cervical traction device must be signed and dated by the treating physician, kept on file by the supplier, and be 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.

**KX, GA, AND GZ MODIFIERS:**

Suppliers must add a KX modifier to code E0849 or E0855 only if all of the criteria in the "Indications and Limitations of Coverage and/or Medical Necessity" section of this policy have been met and evidence of such is maintained in the supplier's files. This information must be available upon request.

If all of the criteria in the Indications and Limitations of Coverage and/or Medical Necessity section have not been met, the GA or GZ modifier must be added to the code. When there is an expectation of a medical necessity denial, suppliers must enter the GA modifier on the claim line if they have obtained a properly executed Advance Beneficiary Notice (ABN) or the GZ modifier if they have not obtained a valid ABN.

Claims lines billed without a KX, GA, or GZ modifier will be rejected as missing information.

**MISCELLANEOUS**

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

**Appendices**

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**

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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".

<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>
| 02/04/2011            | R2                      | **Revision Effective Date:** 02/04/2011 (March 2013 Publication)  
Indications and Limitations of Coverage: Revised: Order requirements language to specify a "detailed written order"  
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) | Provider Education/Guidance |
| 02/04/2011            | R1                      | **Revision Effective Date:** 02/04/2011  
Indications and Limitations of Coverage: Deleted: Least costly alternative for multiple codes  
HCPCS Codes and Modifiers: Revised: GA modifier  
**Revision Effective Date:** 09/01/2009  
Indications and Limitations of Coverage: Removed: E0856 from range of covered codes  
HCPCS Codes and Modifiers: Added: GA and GZ modifiers  
Revised: KX modifier  
Documentation Requirements: Added instructions for the use of GA and GZ modifiers | Maintenance (annual review with new changes, formatting, etc.) |
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 L15300 from DME PSC Electronic Data Systems Corp. (77006) LCD L15300.

Revision Effective Date: 01/01/2008
INDICATIONS AND LIMITATIONS OF COVERAGE:
Added: Coverage statement regarding E0856
HCPCS CODES AND MODIFIERS:
Added: E0856

Revision Effective Date: 01/01/2007
INDICATIONS AND LIMITATIONS OF COVERAGE:
Removed references to the DMERC
Expanded allowance for coverage of E0855
Removal of the "Sources of Information"
DOCUMENTATION REQUIREMENTS:
Removed references to the DMERC

Revision Effective Date: 07/01/2006
INDICATIONS AND LIMITATIONS OF COVERAGE:
Separate allowance of coverage of E0855 if both Cervical Traction criteria and the noted additional criteria A and B are met
DOCUMENTATION REQUIREMENTS:
Added requirements for use of KX with E0855
REVISED SOURCES OF INFORMATION AND BASIS FOR DECISION:
Section Updated

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).

Revision Effective Date: 04/01/2005
HCPCS CODES AND MODIFIERS:
K0627 crosswalked to E0849

Associated Documents

Attachments
There are no attachments for this LCD

Related Local Coverage Documents
Article(s)
A16851 - Cervical Traction Devices - Policy Article - Effective April 2013

Related National Coverage Documents

All Versions
Updated on 03/01/2013 with effective dates 02/04/2011 - N/A
Updated on 03/08/2012 with effective dates 02/04/2011 - N/A
Updated on 12/08/2010 with effective dates 02/04/2011 - N/A
Updated on 08/20/2009 with effective dates 09/01/2009 - 02/03/2011
Updated on 03/13/2008 with effective dates 01/01/2008 - 08/31/2009
Updated on 03/05/2008 with effective dates 01/01/2008 - N/A

Keywords
N/A
ARTICLE: Cervical Traction Devices - Policy Article - Effective April 2013 (A16851)

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").

Cervical traction devices are covered under the Durable Medical Equipment benefit (Social Security Act §1861(s)(6)). In order for a beneficiary’s DME 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.

Cervical orthoses, such as soft or rigid cervical collars, are not considered DME; however, they are eligible for Medicare coverage under the Brace benefit.

CODING GUIDELINES

Code E0855 describes cervical traction devices that provide traction on the cervical anatomy without the use of a door or external frame or stand. Traction may be applied by means of mandibular or occipital pressure.

Code E0860 describes cervical traction devices that provide traction on the cervical anatomy through a system of pulleys and rope and are attached to a door. Traction may be applied in either the upright or supine position.

Code E0849 describes cervical traction devices that provide traction on the cervical anatomy through the use of a free-standing frame. Traction force is applied by means of pneumatic displacement to anatomical areas other than the mandible (e.g., the occipital region of the skull). Devices described by code E0849 must be capable of generating traction forces greater than 20 pounds. In addition, code E0849 devices allow traction to be applied with alternative vectors of force (e.g., 15 degrees of lateral neck flexion).

Suppliers should contact the Pricing, Data Analysis and Coding (PDAC) Contractor for guidance on the correct coding of these items.

CODING INFORMATION

Other Information

Revision History Explanation
Revision Effective Date: 04/01/2013
NONMEDICAL NECESSITY COVERAGE AND PAYMENT RULES:
Added: Preamble
Added: DME benefit category statement

Revision Effective Date: 09/01/2009
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 A16851 from DME PSC Electronic Data Systems Corp. (77006) Article A16851.

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: 04/01/2005
CODING GUIDELINES:
K0627 crosswalked to E0849

Related Document(s)
LCD(s)
L15300 - Cervical Traction Devices

All Versions

Updated on 03/01/2013 with effective dates 04/01/2013 - N/A
Updated on 06/20/2009 with effective dates 09/01/2009 - 03/31/2013
Updated on 02/19/2008 with effective dates 03/01/2006 - 08/31/2009

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