

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)
Transmittal 165	Date: OCTOBER 6, 2006
	Change Request 5301

SUBJECT: Durable Medical Equipment Medicare Administrative Contractors (DME MACs) Adoption or Rejection of Local Coverage Determinations (LCDs) Recommended by Durable Medical Equipment Program Safeguard Contractors (DME PSCs)

I. SUMMARY OF CHANGES: DME PSCs shall recommend LCDs to the DME MACs for adoption or rejection.

NEW / REVISED MATERIAL

EFFECTIVE DATE: For the DMERCs - **SEPTEMBER 11, 2006**

For the DME MACs – Effective upon release of the Contract Modification

IMPLEMENTATION DATE: October 26, 2006

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revise information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS:

R=REVISED, N=NEW, D=DELETED

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	13/TOC
R	13/13.1.3/Local Coverage Determinations (LCDs)
N	13/13.1.4/Durable Medical Equipment Medicare Administrative Contractors (DME MACs) Adoption or Rejection of LCDs Recommended by Durable Medical Equipment Program Safeguard Contractors (DME PSCs).

III. FUNDING:

Additional funding will be provided by CMS to contractors through the regular budget process.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

**Unless otherwise specified, the effective date is the date of service.*

Attachment - Business Requirements

Pub. 100-08	Transmittal: 165	Date: October 6, 2006	Change Request 5301
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SUBJECT: Durable Medical Equipment Medicare Administrative Contractors (DME MACs) Adoption or Rejection of Local Coverage Determinations (LCDs) Recommended by Durable Medical Equipment Program Safeguard Contractors (DME PSCs)

I. GENERAL INFORMATION

A. Background: The DME PSCs shall ensure that LCDs they recommend to the DME MACs are developed and revised in accordance with Pub.100-08, chapter 13. This CR adds a new section to chapter 13 which applies to the: 1) DME PSCs that develop new policies and revise existing policies; 2) DME MACs; and 3) DMERCs that have not yet transitioned to the DME MACs. All references made to DME MACs in this section apply to DMERCs.

B. Policy: This CR provides information on LCDs that will be recommended by the DME PSCs to the DME MACs for adoption or rejection. The DME PSCs shall develop new policies and revise existing adopted policies that are consistent with all applicable Medicare statutes, rulings, regulations, and national coverage, payment, and coding policies and submit the recommended LCDs to the DME MACs for adoption or rejection.

II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement
"Should" denotes an optional requirement

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		F I	R H I	C a r r i e r	D M E R C / D M E M A C	Shared System Maintainers				Other –DME PSC
					F I S S	M C S	V M S	C W F		
5301.1	The DME PSCs shall have on-going communication with the DME MACs as a new policy is being developed or when an existing adopted policy is being revised.				X					X

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R H I	C a r r i e r	D M E R R C / D M E M A C	Shared System Maintainers				Other –DME PSC
F I S S	M C S					V M S	C W F			
5301.2	The DME PSCs shall develop identical LCDs.									X
5301.3	The DME PSCs shall maintain an LCD record as a new policy is being developed or when an existing adopted policy is being revised.									X
5301.4	The DME PSCs shall submit a copy of the final draft of the recommended LCD and the LCD record to the DME MACs prior to adoption of the recommended LCD.									X
5301.5	The DME MACs shall ensure that the LCD record is received prior to adoption of the recommended LCD.				X					
5301.6	The DME MACs shall have someone available with a clinical background to review the recommended LCD by the DME PSCs and determine if the recommended LCD shall be adopted or rejected.				X					
5301.7	The DME MACs shall have on-going communication and coordination with the other DME MACs to ensure that all recommended LCDs are consistently reviewed for adoption or rejection across all DME MAC jurisdictions.				X					
5301.8	The DME MACs shall notify the DME PSCs of their decision to adopt or reject the recommended LCD.				X					X

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R H I	C a r r i e r	D M E R C / D M E M A C	Shared System Maintainers				Other –DME PSC
F I S S	M C S					V M S	C W F			
5301.9	If the DME MACs reject the recommended LCD by the DME PSCs, they shall explain in writing to the DME PSCs why the LCD was rejected.				X					X
5301.10	If the DME PSCs decide to modify the rejected LCD based on comments received from the DME MACs, the DME PSCs shall make the appropriate modifications and shall submit a final copy of the recommended LCD to the DME MACs.				X					X
5301.11	The DME PSCs shall publish the adopted LCD via the MCD.									X
5301.12	The DME MACs shall provide an Internet link on their contractor Web site to the MCD to provide access to the adopted LCD.				X					
5301.13	If an aggrieved party challenges an adopted LCD, the DME PSCs shall support the DME MACs in their efforts to defend the adopted LCD during the appeal.				X					X
5301.14	The DME MACs shall provide the LCD record received from the DME PSCs to the ALJ when an LCD is challenged as outlined in Pub. 100-08, Chapter 13, section 13.13.2.				X					

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)							
		F I	R H I	C a r r i e r	D M E R C / D M E M A C	Shared System Maintainers			
F I S S	M C S					V M S	C W F		
	None.								

IV. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: N/A

X-Ref Requirement #	Instructions

B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

V. SCHEDULE, CONTACTS, AND FUNDING

<p>Effective Date*: For the DMERCs - September 11, 2006 For the DME MACs - Effective upon release of the contract modification</p> <p>Implementation Date: October 26, 2006</p> <p>Pre-Implementation Contact(s): Camille Soondar (camille.soondar@cms.hhs.gov)</p> <p>Post-Implementation Contact(s): Regional offices</p>	<p>Additional funding will be provided by CMS to contractors through the regular budget process.</p>
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Medicare Program Integrity Manual

Chapter 13 – Local Coverage Determinations

Table of Contents *(Rev.165, 10-06-06)*

13.1.4 – Durable Medical Equipment Medicare Administrative Contractors (DME MACs) Adoption or Rejection of Local Coverage Determinations (LCDs) Recommended by Durable Medical Equipment Program Safeguard Contractors (DME PSCs)

13.1.3 - Local Coverage Determinations (LCDs)

(Rev.165, Issued: 10-06-06, Effective: 09-11-06, Implementation: 10-26-06)

Section 522 of the Benefits Improvement and Protection Act (BIPA) created the term “local coverage determination” (LCD). An LCD is a decision by a *Medicare administrative contractor (MAC)*, fiscal intermediary or carrier whether to cover a particular service on a *MAC-wide*, intermediary wide or carrier-wide basis in accordance with Section 1862(a)(1)(A) of the Social Security Act (i.e., a determination as to whether the service is reasonable and necessary). The difference between LMRPs and LCDs is that LCDs consist of only “reasonable and necessary” information, while LMRPs may also contain benefit category and statutory exclusion provisions.

The final rule establishing LCDs was published November 11, 2003. Beginning December 7, 2003, local policies will be referred to as LCDs with the understanding of the relative standing of both LCDs and LMRPs. Effective December 7, 2003, contractors will issue LCDs instead of LMRPs. Additionally, over a 2 year period, contractors converted all existing LMRPs into LCDs. Until that conversion was complete, the term LCD, for the purpose of section 522 challenges, will refer to both:

- 1) Reasonable and necessary provisions of an LMRP and,
- 2) An LCD that contains only reasonable and necessary language.

The CMS has developed an application within the Medicare coverage database back-end that will facilitate this conversion. This application was made available to contractors on or about December 3, 2003. The contractor converted the pertinent LMRP information into an LCD and place the remaining information (benefit category, statutory exclusion, and coding provisions) in an article or delete it. Statutory exclusion and benefit category provisions in LMRPs existing before December 7, 2003, remained in effect until that policy is converted into an LCD.

Effective December 7, 2003, contractors directed to no longer create new LMRPs and shall instead create LCDs. All LMRP were converted to LCDs no later than December 2005. Any non-reasonable and necessary language a contractor wishes to communicate to providers were published through an article. Any draft LMRPS that are in the notice period before December 7, 2003, were entered into the MCD as a draft LCD. The draft LCD will then be released as a final LCD on the scheduled effective date. Additionally, when making the conversion from LMRP to LCD, contractors shall also research and revise their manual references in order to ensure their accuracy. Until all CMS manuals are revised, LMRPs will have the same effect as LCDs.

Codes describing what is covered and what is not covered can be part of the LCD. This includes, for example, lists of HCPCS codes that spell out which services the LCD applies to, lists of ICD-9-CM codes for which the service is covered, lists of ICD-9 codes for which the service is not considered reasonable and necessary, etc. These coding descriptions should only be included if they are integral to the discussion of medical necessity.

Coding guidelines are not elements of LCDs and should be published in articles or deleted. Inclusion in LCDs may mislead the public that they can be challenged under the 522 provision. The following are examples of coding guidelines:

A provision stating that a 4-inch thick mattress should be billed using code XXYZ.

A statement that in order to be correctly coded a level X visit shall include complex medical decision making and a review of systems.

The LCDs specify under what clinical circumstances a service is considered to be reasonable and necessary. They are administrative and educational tools to assist providers in submitting correct claims for payment. Contractors publish LCDs to provide guidance to the public and medical community within their jurisdictions. Contractors develop LCDs by considering medical literature, the advice of local medical societies and medical consultants, public comments, and comments from the provider community. (See section 13.7.1 of this chapter.)

The contractor should adopt LCDs that have been developed individually or collaboratively with other contractors. The contractor shall ensure that all LCDs are consistent with all statutes, rulings, regulations, and national coverage, payment, and coding policies.

Any policy developed between February 1, 2001 and December 7, 2003, that has not been converted to an LCD shall be in the format described in PIM Exhibit 6. Additional information on the LCD format is available on the Fu & Associates Web page.

Contractors shall ensure that LCDs present an objective and positive statement and do not malign any segment of the medical community. LCDs do not address fraud and contractors should not use terms such as "fraud" and "fraudulent" in their LCDs. For example, the following sentence would be inappropriate in an LCD. "If, on postpay review this carrier finds that XYZ procedure was billed to Medicare after the effective date of this LCD, it will consider that billing fraudulent." This sentence would be more accurate and less inflammatory if the word "fraudulent" were replaced with the phrase "not reasonable and necessary".

13.1.4 – Durable Medical Equipment Medicare Administrative Contractors (DME MACs) Adoption or Rejection of Local Coverage Determinations (LCDs) Recommended by Durable Medical Equipment Program Safeguard Contractors (DME PSCs)
(Rev.165, Issued: 10-06-06, Effective: 09-11-06, Implementation: 10-26-06)

The DME PSCs shall ensure that the LCDs they recommend to the DME MACs are developed and revised in accordance with this chapter. This section applies to the:

- DME PSCs that develop new policies and revise existing policies.*
- DME MACs.*
- DMERCs that have not yet transitioned to the DME MACs. (All references made to DME MACs in this section apply to DMERCs.)*

The DME PSCs shall have on-going communication with the DME MACs as a new policy is being developed or when an existing adopted policy is being revised. CMS requires that the recommended LCDs developed by the DME PSCs be identical for each region to ensure uniformity for DMEPOS suppliers that operate nationally. The DME PSCs shall maintain an LCD record as a new policy is being developed or when an existing adopted policy is being revised. The DME PSCs shall submit a copy of the final draft of the recommended LCD and the LCD record to the DME MACs prior to adoption of the recommended LCD. The DME MACs shall ensure that the LCD record is received prior to adoption of the recommended LCD. The LCD record shall consist of any document or material that the DME PSCs considered during the development of the new or revised LCD, including, but not limited to, the following:

- 1. Any medical evidence considered on or before the date the LCD was recommended to the DME MACs for adoption, including, but not limited to, the following:*
 - Scientific articles.*
 - Technology assessments.*
 - Clinical guidelines.*
 - Documentation from the FDA regarding safety and efficacy of a drug or device with the exception of proprietary data and privileged information.*
 - Statements from clinical experts, medical textbooks, claims data, or other indication of medical standard of practice.*
- 2. Comment and Response Documents (a summary of all comments received by the DME PSCs concerning the recommended LCD). This applies only to new LCDs or revised LCDs that were sent for comment.*

The DME MACs shall have someone available with a clinical background to review the recommended LCD by the DME PSCs and determine if the recommended LCD shall be

adopted or rejected. The DME MACs shall have on-going communication and shall coordinate with the other DME MACs to ensure that a uniform decision is made to adopt or reject a recommended LCD across all DME MAC jurisdictions. The DME MACs shall notify the DME PSCs of their decision to adopt or reject the recommended LCD. The DME MACs shall ensure that the adopted LCDs are identical among the DME MACs.

If the DME MACs reject the recommended LCD by the DME PSCs, they shall explain in writing to the DME PSCs why the LCD was rejected. If the DME PSCs decide to modify the rejected LCD based on comments received from the DME MACs, the DME PSCs shall make the appropriate modifications and shall submit a final copy of the recommended LCD to the DME MACs.

In addition, the DME PSCs shall publish the adopted LCD via the MCD. The MCD shall be updated to ensure that the “Contractor Information Section” of the adopted LCD indicates that the LCD was “adopted” by the DME MACs. The DME MACs shall provide an Internet link on their contractor Web site to the MCD to provide access to the adopted LCD.

If an aggrieved party challenges an adopted LCD, the DME PSCs shall support the DME MACs in their efforts to defend the adopted LCD during the appeal. For example, if the DME MACs need the DME PSCs to provide oral testimony during an appeal, the DME PSCs shall provide such testimony. Questions concerning the extent of the DME PSCs’ support to the DME MACs during the appeals process shall be directed to the appropriate Primary and/or Associate GTL(s). The DME MACs shall provide the LCD record received from the DME PSCs to the ALJ when an LCD is challenged as outlined in section 13.13.2 of this chapter.

As referenced in Pub. 100-08, chapter 4, section 4.28, the joint operating agreement developed by the DME PSCs and the DME MACs shall be modified to address the major roles and responsibilities DME PSCs and DME MACs will delineate in order for the DME MACs to adopt or reject LCDs recommended by the DME PSCs.