

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)
Transmittal 302	Date: September 11, 2009
	Change Request 6586

SUBJECT: Local Coverage Determinations (LCD) Exceptions

I. SUMMARY OF CHANGES: During complex medical review ACs, MACs, RACs, and CERT have to apply LCDs when reviewing claims. This CR provides the authority to apply an exception to the clinical reasonable and necessary requirements of an LCD in rare and unusual circumstances.

New / Revised Material

Effective Date: October 13, 2009

Implementation Date: October 13, 2009

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/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	3/Table of Contents
N	3/3.12/LCD Exceptions

III. FUNDING:

SECTION A: For Fiscal Intermediaries and Carriers:

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

SECTION B: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

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

Attachment - Business Requirements

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SUBJECT: Local Coverage Determinations (LCD) Exceptions

Effective Date: October 13, 2009

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I. GENERAL INFORMATION

A. Background: Local coverage determinations are determinations made by a fiscal intermediary, carrier, or MAC respecting whether or not a particular item or service is covered on an intermediary-, carrier-, or MAC-wide basis. LCDs specify under what circumstances a service is generally considered to be reasonable and necessary. In rare and unusual circumstances during complex medical review MACs, FIs and carriers have the authority to apply an exception to the clinical criteria described in an LCD.

B. Policy: Contractors are directed to create LCDs.

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M M A C	F I	C A R I E R	R H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
6586.1	In rare and unusual circumstances, contractors have the authority to apply an exception to the clinical criteria described in an LCD for individual claims	X	X	X	X	X					CERT RAC
6586.2	Contractors shall base their exceptions requests on a thorough review of the patient's medical record and the relevant evidence in the medical literature.	X	X	X	X	X					CERT RAC
6586.3	Contractors other than RACs shall use this process for the purposes of approving or denying an individual claim. RACs shall only use the exception process to not deny an individual claim.	X	X	X	X	X					CERT RAC
6586.4	Contractors shall document in a log the individual claims that are approved or denied based on an LCD exception.	X	X	X	X	X					CERT RAC

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I	C A R I E R	R H H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
	None.										

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements, use the box below:

Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: For all other recommendations and supporting information, use this space:

V. CONTACTS

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Post-Implementation Contact(s): Jesse Polansky, Jesse.Polansky@cms.hhs.gov, 410-786-1171

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs)*, *Regional Home Health Intermediaries (RHHIs)*, and/or *Carriers*:

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

Section B: For *Medicare Administrative Contractors (MACs)*, include the following statement:

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

Medicare Program Integrity Manual

Chapter 3 - Verifying Potential Errors and Taking Corrective Actions

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(Rev.302, 09-11-09)

3.12 – Local Coverage Determination (LCD) Exceptions

3.12 – Local Coverage Determination (LCD) Exceptions **(Rev.302, Issued: 09-11-09, Effective: 10-13-09, Implementation: 10-13-09)**

In rare and unusual circumstances during complex medical review, ACs, MACs, CERT, and RACs have the authority to apply an exception to the clinical reasonable and necessary requirements described in an LCD. Exceptions cannot be made for missing or insufficient documentation. ACs, MACs, and CERT can use the exceptions process to approve or deny a claim. Unless otherwise directed by CMS, RACs can only use the exceptions process to not deny a claim. ACs, MACs, CERT, and RACs shall not make exceptions to NCDs, CMS manuals, or MAC articles.

The ACs, MACs, CERT, and RACs shall exercise their exception authority only after a thorough review of the patient's medical record and a comprehensive analysis of the evidence in the medical literature. The reviewer shall document the specific claim and detail the rationale for the exception in a log maintained at the contractor. Relevant citations to the evidence based literature shall be included in the log. The AC and MAC exception logs shall be accessible to the AC and MAC appeal units. In addition, this log shall be available to CERT, RACs, and CMS upon request.

If exceptions to LCDs are not rare, the contractor shall reevaluate the LCD clinical criteria to ensure that the policy is clear, comprehensive, and current. On an annual basis the AC, MAC, CERT, and RAC contractors shall create an exceptions report and provide it to their project officer, if requested.